## 1 Research protocol: part 1

#### 2 Title

- 3 Evaluation for effectiveness of lidocaine with epinephrine irrigation in reducing acute pain from
- 4 surgical removal of mesioangular-impacted third molars

## 5 **Project Summary**

- 6 Postoperative pain is a common side effect of mandibular third molar surgery. Consequently, local
- 7 anesthetics must be applied to the area of the surgical incision before suturing to relieve any
- 8 associated levels of pain. Thus, this study aimed to compare the efficacy of lidocaine and
- 9 bupivacaine in combination with vasoconstrictors in managing local pain and trismus following
- impacted third molar surgery. Participants aged 18-25 years with similar lower impacted third
- molars were randomly divided to receive 2% lidocaine or 0.5% bupivacaine (n = 17 each) post-
- operatively. Either molar side was randomly selected for the initial surgery and flushed with
- anesthetics before suture removal. Patients were then evaluated for pain levels using the Visual
- Analog Scale (VAS) tool and asked to respond to questionnaires at two, four, six, and eight hours.
- Another tooth was surgically extracted after four weeks and patients were again monitored, as they
- had been for the previous surgery. The findings imply that bupivacaine could alleviate the pain
- associated with mandibular third molar surgery more effectively than lidocaine.

#### 18 General Information

#### 19 *Protocol title*:

- 20 Anesthetic Efficacy of Lidocaine and Bupivacaine Following Lower Third Molar Extraction: A
- 21 Comparative Evaluation (Certificate Number: 42/2016, Date: August 24<sup>th</sup>, 2016).

#### 22 Name and address of the sponsor/funder:

- 23 Residency Training Program in Oral and Maxillofacial Surgery, Faculty of Dentistry, Chiang Mai
- 24 University.

#### Name and title of the investigator(s):

Investigator	Address	Responsibility
1. Vuttinun Chatupos, D.D.S.	Department of Oral and	Supervisor, Surgeon,
Assistant Professor	Maxillofacial Surgery,	Conceptualization,
	Faculty of Dentistry,	Ethics, Consent
	Chiang Mai University,	information, Project
	Chiang Mai, Thailand	administration,
		Discussion
2. Sumatee Yuthavong, D.D.S.	Department of Oral and	Clinical investigator,
	Maxillofacial Surgery,	Dentist, Data collector
	Faculty of Dentistry,	

	Chiang Mai University,	
	Chiang Mai, Thailand	
3. Yanisa Naruenartwongsakul, D.D.S.	Department of Oral and	Clinical investigator,
5. Tumbu Turuchartwongsanar, 2.2.5.	Maxillofacial Surgery,	Dentist, VAS
	Faculty of Dentistry,	measurement, Data
	Chiang Mai University,	collector
	Chiang Mai, Thailand	
4. Pratchanun Sanjitt, D.D.S.	Department of Oral and	Clinical investigator,
,	Maxillofacial Surgery,	Dentist, VAS
	Faculty of Dentistry,	measurement, Data
	Chiang Mai University,	collector
	Chiang Mai, Thailand	
5. Mayuree Kuraoka, D.D.S.	Department of Oral and	Clinical investigator,
,	Maxillofacial Surgery,	Dentist, VAS
	Faculty of Dentistry,	measurement, Data
	Chiang Mai University,	collector
	Chiang Mai, Thailand	
6. Ittiwat Pooripoosit, D.D.S.	Department of Oral and	Clinical investigator,
-	Maxillofacial Surgery,	Dentist, VAS
	Faculty of Dentistry,	measurement, Data
	Chiang Mai University,	collector
	Chiang Mai, Thailand	
7. Pakamon Chutchawalkijkul, D.D.S.	Department of Oral and	Clinical investigator,
	Maxillofacial Surgery,	Dentist, VAS
	Faculty of Dentistry,	measurement, Data
	Chiang Mai University,	collector
	Chiang Mai, Thailand	
8. Pattaranee Srichairatanakool, MD.	Department of	Conceptualization,
	Biochemistry, Faculty of	Anesthesiologist,
	Medicine, Chiang Mai	Clinical investigator
	University, Chiang Mai,	
	Thailand	
9. Wachiraporn Tipsuwan, PhD.	Department of	Researcher, Data
Assistant Professor	Biochemistry, Faculty of	analysis, Report
	Medicine, Chiang Mai	writing, Discussion
	University, Chiang Mai,	
	Thailand	
10. Somdet Srichairatanakool, Ph.D.	Department of	Conceptualization,
Professor	Biochemistry, Faculty of	Researcher, Data
	Medicine, Chiang Mai	analysis, Report
	University, Chiang Mai,	writing, Discussion
	Thailand	

## Name(s) and address(es) of the clinical laboratory:

- Out-Patient Department Number 3, Department of Oral and Maxillofacial Surgery, Faculty
   of Dentistry, Chiang Mai University, Chiang Mai, Thailand
- 2. Oxidative Stress Laboratory, Department of Biochemistry, Faculty of Medicine, Chiang Mai
   University, Chiang Mai Thailand

#### Rationale & Background Information

Mandibular third molars typically erupt in humans between 18 and 24 years of age. Accordingly, the lower third molar will commonly become impacted and will have to be removed. However, discomfort and certain adverse effects may occur following an impacted tooth extraction such as edema, numbness, and excessive bleeding. Pain is the most prevalent problem following impacted tooth extractions [1, 2], which is a complex phenomenon characterized by a substantial subjective component and is dependent upon several endogenous and exogenous factors [3]. Pain perception affects individuals differently depending upon certain psychosocial biological variables [4]. The pain experienced from dental extraction and dental anesthesia can produce different responses among patients.

In clinical use, local anesthesia (LA) can relieve the pain associated with certain surgical procedures, but their use may also become a source of anxiety and may contribute to the discomfort a patient undergoes [5]. Lidocaine or 2-(diethylamino)-N-(2,6-dimethylphenyl) acetamide is a common local anesthetic drug that is widely used in dentistry to alleviate the sensation of pain generating from specific body areas during surgery or dental work. Functionally, lidocaine blocks the fast voltage-gated Na<sup>+</sup> channels in nerve cell membranes to prevent the initiation and conduction of nerve impulses that transmit pain signals to the brain [6]. Regarding its bioavailability, elimination half-life values of lidocaine are approximately 15-2 hours for intravenous administration and 1.5-2.5 hours for subcutaneous administration [7]. However, certain side effects, including redness, swelling, itching, dizziness, drowsiness, nausea, and, rarely, severe allergic reactions, have been observed [8]. Tuffin and colleagues have previously reported that 0.75% bupivacaine reduced pain scores after impacted tooth extraction but did not decrease the degree of analgesic drug intake [9]. In addition, Reza et al. found that irrigation of the tooth socket with 0.5% bupivacaine after removal of the impacted third molar could significantly reduce the discomfort of the patient when compared to normal saline irrigation [1].

These outcomes demonstrate that local anesthesia for impacted tooth lesions can effectively reduce short-term sensations of pain after surgery [10]. The previous research findings also indicate that the anesthetic can penetrate the oral mucosa. Smeared or sprayed local anesthetics, such as lidocaine, benzocaine, and butacaine, only numb the epithelium, while the deeper tissues cannot be anesthetized. A visual analog scale (VAS) is a pain-rating scale that is often used in dentistry and clinical research to measure the intensity or frequency of pain, specifically the pain associated with postoperative tooth extraction [11-13].

## **Hypothesis**

Lidocaine would exert not only systemic anesthetic but also local anti-pain property to be used in postoperative patients with mesioangular impacted molars.

#### **Study Goals and Objectives**

1. To select the appropriate local anesthetic for mandibular third molar surgery

- 2. To evaluate and compare the analgesic effects of lidocaine and bupivacaine after mandibular third molar surgery
- 3. To compare anti-pain and would healing effects of lidocaine plus epinephrine irrigation with NSS solution irrigation in patients after surgical removal of mandibular third molars

#### **Ethics**

This study received approval from the Human Experimentation Committee Research Institute for Health Sciences and signed by Professor Dr. Anak Iamaroon, D.D.S., M.S., Ph.D., a Chairman of the Committee, Faculty of Dentistry, Chiang Mai University, Chiang Mai 50200, Thailand (Certificate Number: 52/2014 (52/2557 for Thai version), Date: 3<sup>rd</sup> December 2014 and Certificate Number: 42/2016, Date: 24<sup>th</sup> August 2016). Adherence to ethical guidelines was a prime importance throughout the study process. All patients were fully informed about the particulars of the study and willingly provided their signatures on the consent forms before any study procedures were performed. This study followed the guidelines of the Helsinki Declaration 2008, revised in 2013: Ethical Principles for Medical Research Involving Human Subjects. Subjects' rights have been protected by an appropriate Institutional Review Board and written informed consent was granted from all subjects.

### **Study Design**

Subjects: All A total of 34 patients who were orthodontically indicated for bilateral impacted lower molar extraction were chosen for this study. The participants were enrolled at Out-Patient Department Number  $\frac{3}{5}$ , Department of Oral and Maxillofacial Surgery, Faculty of Dentistry, Chiang Mai University, Chiang Mai, Thailand between  $\frac{01}{10}$  and  $\frac{30}{9}$ 2016. The patients' mouths were divided into two sections, one section was bathed with lidocaine (n = 17) and the other was doused with bupivacaine (n = 17).

#### **Inclusion Criteria:**

Individuals aged between 18 and 25 years were included in this study who were systemically deemed to be healthy and orthodontically indicated for impacted lower third molar on both sides as depicted in panoramic radiographs. Individuals were selected who were non-allergic to amoxicillin and paracetamol and who had not previously experienced inflammation or infection of the teeth and gums around the lower molars before treatment.

#### **Exclusion Criteria:**

Individuals with a history of neurological disorders, allergies to lidocaine and bupivacaine, and those who had received steroid medication were excluded from the study.

#### **Discontinuation Criteria:**

- Patients could give up or withdraw from the study at any time.
- Unable to revisit for next follow-up

#### Methodology

#### Sample Size Calculation

This is a comparative study that endeavors to identify the anesthetic and analgesic properties of lidocaine and bupivacaine. Sample size was calculated by using the STATA® version 16.0 software (StataCorp, LLC, College Station, TX, USA). A total of 34 patients who were

orthodontically indicated for bilateral impacted lower molar extraction were chosen for this study. The participants were enrolled at Out-Patient Department Number 3 (OPD 3), Department of Oral and Maxillofacial Surgery, Faculty of Dentistry, Chiang Mai University, Chiang Mai, Thailand between September 2019 and March 2020. This study was conducted after obtaining written informed consent from all participants and ethical approval from the Institutional Human Experimentation Committee.

## Study Intervention

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The patients' mouths were divided into two sections, one section was bathed with lidocaine (n = 17) and the other was doused with bupivacaine (n = 17). The time was recorded when the inferior alveolar nerve block was initiated with anesthetics in combination with the vasoconstriction drug. Each step of the wisdom tooth extraction process was timed, beginning with the flap opening, and subsequently, bone filling, tooth division, and root picking (for fractured roots) on both sides of the mouth. Both the amounts of anesthetics that were administered and the number of sutures used were recorded. Before sealing the flap, the lingual and buccal sites were thoroughly dried with gauze and any blood was suctioned away. Afterward, the wound was rinsed with 3.6 mL of 2% lidocaine or 0.5% bupivacaine (double-blind operation) with epinephrine (1:200,000) for 3-5 minutes, and then aspirated with the anesthetic drug. The participants were instructed to care for their wounds following wisdom tooth extraction, record pain levels using the VAS tool at 2, 4, 6, and 8 hours, and complete the study on the day of the stitch-off. In terms of medication, subjects were prescribed to take one capsule of amoxicillin (500 mg) after meals and before bedtime with or without one paracetamol (500 mg) tablet every 6 hours. If taken, the amount and duration of the paracetamol being prescribed were recorded. Three weeks later, molar extraction on the other side of the mouth was scheduled and performed as has been previously described. The consolidated standards of the reporting trial (CONSORT) flow diagram for this study have been presented in Figure 1.

#### Postoperative Medication

Regarding medication, subjects were prescribed one ampicillin capsule after meals and before bedtime with or without one paracetamol tablet every 6 hours. If taken, the amounts and duration of the paracetamol being prescribed were recorded. Three weeks later, molar extraction on the other side of the mouth was scheduled and performed as has been previously described. The consolidated standards of the reporting trial (CONSORT) flow diagram of this study have been presented in Figure 1.

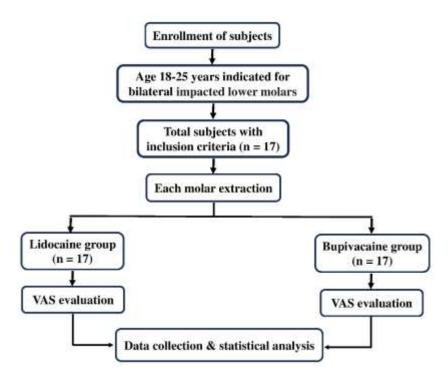


FIGURE 1: CONSORT flow diagram of the study design. CONSORT = consolidated standards of the reporting trial.

#### VAS Assessment

 The degree of pain intensity that subjects felt was marked on a VAS of 0-10, with 0 being no pain and 10 representing maximum pain [11]. For evaluation, a VAS recording sheet was used by the researcher to record pain levels at appropriate time intervals covering 2-8 hours post-operation, according to the frequency and severity of each patient's pain.

## Data Management and Statistical Analysis

Data were analyzed and the statistical significance was determined using the SPSS Statistics version 22 program (IBM, SPSS Inc., Chicago, IL, USA), for which the significance was set at p < 0.05. Repeated measures for analysis of variance (ANOVA) were used to compare the overall treatment effects of bupivacaine and lidocaine in terms of pain intensity (VAS score) at various time intervals following molar extraction. A paired Student's t-test was used to compare the median scores of pain intensity at various time intervals after the alveolar nerve block was initiated. When the data were not indicative of normal distribution levels, a non-parametric Wilcoxon Signed Rank test was used to compare the mean pain scale values between the two drugs.

#### References

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## Quality assurance

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- 203 The protocol should describe the quality control and quality assurance system for the conduct of
- 204 the study, including guideline for clinical practice (GCP), follow up by clinical monitors, data and
- safety monitoring board (DSMB) guidelines, data management etc.

#### **Expected outcomes of the study**

- 1. Bupivacaine could alleviate pain after mandibular third molar surgery more effectively than lidocaine
  - 2. Irrigation of lidocaine combined with epinephrine could be more effective than normal saline solution in suppressing and relieving acute postoperative pain in patients undergoing the surgical removal of impacted mesioangular third molars

3. Irrigation of lidocaine combined with epinephrine could promote the periodontal healing of in patients with post-operational molar extraction(s)

## Dissemination of results and publication policy

The protocol should specify not only dissemination of results in the scientific media, but also to the community and/ or the participants, and consider dissemination to the policy makers where relevant. Publication policy should be clearly discussed- for example who will take the lead in publication and who will be acknowledged in publications, etc.

## **Duration of the project:** 2 years and 9 months (01/10/2014 – 30/06/2017)

Activities	2014	2014 2015		2016				2017			
	Oct- Dec	Jan- Mar	Apr- Jun	Jul- Sep	Oct- Dec	Jan- Mar	Apr- Jun	Jul- Sep	Oct- Dec	Jan- Mar	Apr- Jun
Wrote a study protocol											
2. Submitted a proposal for human experimentation											
3. Revised the proposal											
4. Approved the Human Ethical Clearance											
5. Lidocaine plus epinephrine irrigation vs NSS											
5.1 Recruited patients with impacted third molar											
5.2 Surgical removal of lower mandibular molars											
5.3 Assessed VAS values											
5.4 Data analysis											
6. Comparison between bupivacaine and lidocaine											
6.1 Recruited patients with impacted third molar											
6.2 Approved the Human Ethical Clearance											
6.3 Surgical removal of lower mandibular molars											
6.4 Assessed VAS values											
6.5 Data analysis											
7. Report results to the ethical committee											

## **Problems anticipated**

This section should discuss the difficulties that the investigators anticipate in successfully completing their projects within the time frame stipulated and the funding requested. It should also offer possible solutions to deal with these difficulties.

## **Project management**

Investigator	Responsibility
1. Vuttinun Chatupos, D.D.S.	Supervisor, Surgeon, Conceptualization,
Assistant Professor	Ethics, Consent information, Project
	administration, Discussion
2. Sumatee Yuthavong, D.D.S.	Clinical investigator, Dentist, Data collector
3. Yanisa Naruenartwongsakul, D.D.S.	Clinical investigator, Dentist, VAS
_	measurement, Data collector
4. Pratchanun Sanjitt, D.D.S.	Clinical investigator, Dentist, VAS
	measurement, Data collector

5. Mayuree Kuraoka, D.D.S.	Clinical investigator, Dentist, VAS
	measurement, Data collector
6. Ittiwat Pooripoosit	Clinical investigator, Dentist, VAS
	measurement, Data collector
7. Pakamon Chutchawalkijkul	Clinical investigator, Dentist, VAS
	measurement, Data collector
8. Pattaranee Srichairatanakool	Conceptualization, Anesthesiologist,
	Clinical investigator
9. Wachiraporn Tipsuwan	Researcher, Data analysis, Report writing,
	Discussion
10. Somdet Srichairatanakool, Ph.D.	Conceptualization, Researcher, Data
Professor	analysis, Report writing, Discussion

#### 225 Ethics

- 226 Ethical approval for this project was granted by the Human Experimentation Committee of the
- 227 Faculty of Dentistry, Chiang Mai University, Chiang Mai, Thailand (Certificate Number:
- 52/2014 (52/2557 for Thai version), Date: 3<sup>rd</sup> December 2014 and Certificate Number:
- 42/2016, Date: 24<sup>th</sup> August 2016). All patients were fully informed about the particulars of the
- study and willingly provided their signatures on the consent forms before any study procedures
- were performed. This study followed the guidelines of the Helsinki Declaration 2008: Ethical
- 232 Principles for Medical Research Involving Human Subjects. Subjects' rights have been protected
- by an appropriate institutional review board and written informed consent was granted by all
- subjects.

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#### **Informed Consent Form (ICF)**

- Title of Study: Evaluation for effectiveness of lidocaine with epinephrine irrigation in reducing acute pain from surgical removal of mesioangular-impacted third molars
- Purpose of Study: To select the appropriate local anesthetic for mandibular third molar surgery and evaluate and compare the analgesic effects of lidocaine and bupivacaine after mandibular third molar surgery.

#### 241 Principal Investigator

- Name: Dr. Vuttinun Chatupos, D.D.S. Academic Position: Assistant Professor
- 243 Office: Department of Oral and Maxillofacial Surgery, Faculty of Dentistry, Chiang Mai
- 244 University, Chiang Mai 50200, Thailand.
- 245 Telephone: +66 53 944454
- 246 Email: <u>vuttinunch@yahoo.co.th</u>
- 247 Signature
- 248 (Dr. Vuttinun Chatupos, D.D.S.)

d. lutti

249 Date 05 Jan 2015

### Participant 1 (Code MF14)

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- Age 20.4 years old, HN 6613298 Village No. ..... Subdistrict..... 251  $\mathbf{I}$ , น.ส. วันวิสา หายโศรก
- District..... Province..... read the details from the attached information sheet for 252
- research project participants, and I agree to voluntarily participate in the said research project. 253
- 254 I have received a copy of the consent to participate in the research project that I signed and dated,
- along with a document explaining information for research participants. This is before signing the 255
- consent form to conduct this research. I was explained by the researcher about the purpose of the 256
- research. The duration of the research, research methods, dangers or symptoms that may arise from 257
- the research, or from the medicine used Including the benefits that will arise from the research. 258
- 259 and guidelines for treatment by other methods in detail. I have had enough time and opportunity
- 260 to ask questions until I have a good understanding. The researcher answered various questions
- willingly and without concealment until I was satisfied. 261
  - I am informed by the researcher that if there is any danger from such research. I will receive medical treatment free of charge.
  - I have the right to terminate my participation in the research project at any time. You must notify the reason, and termination of participation in this research It will not affect treatment or other rights that I will continue to receive.
  - The researcher guarantees that my personal information will be kept secret, and will be disclosed only with my consent. Other persons on behalf of the research sponsoring company Human Research Ethics Committee. The Food and Drug Administration may be permitted to inspect and process my information. This must be done for the purpose of verifying the accuracy of the information only. By agreeing to participate in this study, I am giving consent to have my medical history reviewed. I understand that I have the right to inspect or correct my personal data and can revoke my authorization to use my personal data. This must be informed to the researcher.
  - I am aware that the research information includes my medical information which is anonymous. It will go through various processes such as collecting data. Recording information in records and on computers, examining, analyzing, and reporting information for academic purposes. Including future use of medical information or pharmaceutical research only.
  - If I have any questions about the research process. I can contact Dr. Sansanee Neelawattanasuk, telephone number 085-000-9468, Department of Oral and Maxillofacial Surgery, Faculty of Dentistry Chiang Mai University, telephone 053-944456 (during official hours).
- I have read all the information and am willing to participate in the clinical research study. 284

285	Signature Jonas N	On behalf of <b>Participant 1</b> (รันวิตา หายโครก)
286	Date 05 Jan 2015	

287 (Dr. Yanisa Naruenartwongsakul, D.D.S), Email: fai.fai.yanisa@gmail.com
288 I have explained the purpose of the research, the research methods, dangers or adverse reactions
289 or risks that may arise from the research. or from the medicine used Including the benefits that will
290 arise from thorough research. Let the participants in the research project named above know and
291 have a good understanding. Ready to sign the consent document willingly.

292 Signature:

Date 05 Jan 2015

Janar N

Researcher: Dr. Yanisa Naruenartwongsakul, D.D.S, Email: fai.fai.yanisa@gmail.com

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## Participant 2 (Code MF15)

- 298 Subdistrict. District. Province.
- read the details from the attached information sheet for research project participants. and I agree to voluntarily participate in the said research project.
- I have received a copy of the consent to participate in the research project that I signed and dated, along with a document explaining information for research participants. This is before signing the consent form to conduct this research. I was explained by the researcher about the purpose of the research. The duration of the research, research methods, dangers or symptoms that may arise from the research. or from the medicine used Including the benefits that will arise from the research. and guidelines for treatment by other methods in detail. I have had enough time and opportunity to ask questions until I have a good understanding. The researcher answered various questions willingly and without concealment until I was satisfied.
  - I am informed by the researcher that if there is any danger from such research. I will receive medical treatment free of charge.
    - I have the right to terminate my participation in the research project at any time. You must notify the reason. and termination of participation in this research It will not affect treatment or other rights that I will continue to receive.
    - The researcher guarantees that my personal information will be kept secret. and will be disclosed only with my consent. Other persons on behalf of the research sponsoring company Human Research Ethics Committee. The Food and Drug Administration may be permitted to inspect and process my information. This must be done for the purpose of verifying the accuracy of the information only. By agreeing to participate in this study, I am giving consent to have my medical history reviewed. I understand that I have the right to inspect or correct my personal data and can revoke my authorization to use my personal data. This must be informed to the researcher.
    - I am aware that the research information includes my medical information which is anonymous. It will go through various processes such as collecting data. Recording information in records and on computers, examining, analyzing, and reporting information

325	for academic purposes. Including future use of medical information or pharmaceutical
326	research only.
327	- If I have any questions about the research process. I can contact Dr. Sansanee
328	Neelawattanasuk, telephone number 085-000-9468, Department of Oral and Maxillofacial
329	Surgery, Faculty of Dentistry Chiang Mai University, telephone 053-944456 (during
330	official hours).
331	I have read all the information and am willing to participate in the clinical research study.
	Varian X
332	Signature On behalf of Participant 2 (น.ส. ภูริชญา กาพพรรณสึก)
333	Date 05 Jan 2015
334	(Dr. Yanisa Naruenartwongsakul, D.D.S), Email: fai.fai.yanisa@gmail.com
335	I have explained the purpose of the research, the research methods, dangers or adverse reactions
336	or risks that may arise from the research. or from the medicine used Including the benefits that
337	will arise from thorough research. Let the participants in the research project named above know
338	and have a good understanding. Ready to sign the consent document willingly.
339	Signature: Vonav. N
340	Date 05 Jan 2015
341	Researcher: Dr. Yanisa Naruenartwongsakul, D.D.S, Email: fai.fai.yanisa@gmail.com
342	Participant 3 (Code MF16)
343	I, น.ส. เกษกนก เรื่องกูล age 20.4 years old, HN: 6512855 Village No
344	Subdistrict District Province
345	read the details from the attached information sheet for research project participants. and I agree
346	to voluntarily participate in the said research project.
347	I have received a copy of the consent to participate in the research project that I signed and dated,
348	along with a document explaining information for research participants. This is before signing the
349	consent form to conduct this research. I was explained by the researcher about the purpose of the
350	research. The duration of the research, research methods, dangers or symptoms that may arise from
351	the research. or from the medicine used Including the benefits that will arise from the research.
352	and guidelines for treatment by other methods in detail. I have had enough time and opportunity
353	to ask questions until I have a good understanding. The researcher answered various questions
354	willingly and without concealment until I was satisfied.
355	- I am informed by the researcher that if there is any danger from such research. I will receive
356	medical treatment free of charge.
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357	- I have the right to terminate my participation in the research project at any time. You must
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The researcher guarantees that my personal information will be kept secret, and will be disclosed only with my consent. Other persons on behalf of the research sponsoring company Human Research Ethics Committee. The Food and Drug Administration may be permitted to inspect and process my information. This must be done for the purpose of verifying the accuracy of the information only. By agreeing to participate in this study, I am giving consent to have my medical history reviewed. I understand that I have the right to inspect or correct my personal data and can revoke my authorization to use my personal data. This must be informed to the researcher.

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- I am aware that the research information includes my medical information which is anonymous. It will go through various processes such as collecting data. Recording information in records and on computers, examining, analyzing, and reporting information for academic purposes. Including future use of medical information or pharmaceutical research only.
- If I have any questions about the research process. I can contact Dr. Sansanee Neelawattanasuk, telephone number 085-000-9468, Department of Oral and Maxillofacial Surgery, Faculty of Dentistry Chiang Mai University, telephone 053-944456 (during official hours).
- I have read all the information and am willing to participate in the clinical research study.

#### 377 Januar N Signature On behalf of Participant 3 (น.ส. เกษกนก เรื่องกูล) 378 379 Date 05 Jan 2015 (Dr. Yanisa Naruenartwongsakul, D.D.S), Email: fai.fai.yanisa@gmail.com 380 I have explained the purpose of the research, the research methods, dangers or adverse reactions 381 or risks that may arise from the research, or from the medicine used Including the benefits that 382 will arise from thorough research. Let the participants in the research project named above know 383 and have a good understanding. Ready to sign the consent document willingly. 384 Janan N 385 Signature: Date 05 Jan 2015 386 Researcher: Dr. Yanisa Naruenartwongsakul, D.D.S., Email: fai.fai.yanisa@gmail.com 387 Participant 4 (Code MF17) 388 I, นาย ธนโชติ สิริจำรัสสกุล age 24.6 years old, HN: 6704920 Village No. 389 Subdistrict...... District...... Province...... 390 read the details from the attached information sheet for research project participants. and I agree 391

to voluntarily participate in the said research project.

I have received a copy of the consent to participate in the research project that I signed and dated, along with a document explaining information for research participants. This is before signing the

consent form to conduct this research. I was explained by the researcher about the purpose of the

research. The duration of the research, research methods, dangers or symptoms that may arise from the research. or from the medicine used Including the benefits that will arise from the research. and guidelines for treatment by other methods in detail. I have had enough time and opportunity to ask questions until I have a good understanding. The researcher answered various questions willingly and without concealment until I was satisfied.

- I am informed by the researcher that if there is any danger from such research. I will receive medical treatment free of charge.
- I have the right to terminate my participation in the research project at any time. You must notify the reason. and termination of participation in this research It will not affect treatment or other rights that I will continue to receive.
- The researcher guarantees that my personal information will be kept secret. and will be disclosed only with my consent. Other persons on behalf of the research sponsoring company Human Research Ethics Committee. The Food and Drug Administration may be permitted to inspect and process my information. This must be done for the purpose of verifying the accuracy of the information only. By agreeing to participate in this study, I am giving consent to have my medical history reviewed. I understand that I have the right to inspect or correct my personal data and can revoke my authorization to use my personal data. This must be informed to the researcher.
- I am aware that the research information includes my medical information which is anonymous. It will go through various processes such as collecting data. Recording information in records and on computers, examining, analyzing, and reporting information for academic purposes. Including future use of medical information or pharmaceutical research only.
- If I have any questions about the research process. I can contact Dr. Sansanee Neelawattanasuk, telephone number 085-000-9468, Department of Oral and Maxillofacial Surgery, Faculty of Dentistry Chiang Mai University, telephone 053-944456 (during official hours).
- I have read all the information and am willing to participate in the clinical research study.

Signature 2 On behalf of Participant 4 (นาย ธนโชติ สิริจำรัสสกุล) (Dr. Yanisa Naruenartwongsakul, D.D.S), Email: fai.fai.yanisa@gmail.com Date 08 Jan 2015 I have explained the purpose of the research, the research methods, dangers or adverse reactions or risks that may arise from the research, or from the medicine used Including the benefits that will arise from thorough research. Let the participants in the research project named above know and have a good understanding. Ready to sign the consent document willingly. Janan N Signature: Date 08 Jan 2015 

Researcher: Dr. Yanisa Naruenartwongsakul, D.D.S., Email: fai.fai.yanisa@gmail.com

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## Participant 5 (Code MF18)

- 436 I, u.a. oswauns nosion age 19.8 years old, HN: 6702948 Village No.
- Subdistrict. District. Province.
- read the details from the attached information sheet for research project participants. and I agree
- to voluntarily participate in the said research project.
- I have received a copy of the consent to participate in the research project that I signed and dated,
- along with a document explaining information for research participants. This is before signing the
- consent form to conduct this research. I was explained by the researcher about the purpose of the
- research. The duration of the research, research methods, dangers or symptoms that may arise from
- the research, or from the medicine used Including the benefits that will arise from the research.
- and guidelines for treatment by other methods in detail. I have had enough time and opportunity
- and guidennes for treatment by other methods in detail. I have had enough time and opportunity
- to ask questions until I have a good understanding. The researcher answered various questions
- willingly and without concealment until I was satisfied.
  - I am informed by the researcher that if there is any danger from such research. I will receive medical treatment free of charge.
  - I have the right to terminate my participation in the research project at any time. You must notify the reason, and termination of participation in this research It will not affect treatment or other rights that I will continue to receive.
  - The researcher guarantees that my personal information will be kept secret. and will be disclosed only with my consent. Other persons on behalf of the research sponsoring company Human Research Ethics Committee. The Food and Drug Administration may be permitted to inspect and process my information. This must be done for the purpose of verifying the accuracy of the information only. By agreeing to participate in this study, I am giving consent to have my medical history reviewed. I understand that I have the right to inspect or correct my personal data and can revoke my authorization to use my personal data. This must be informed to the researcher.
  - I am aware that the research information includes my medical information which is anonymous. It will go through various processes such as collecting data. Recording information in records and on computers, examining, analyzing, and reporting information for academic purposes. Including future use of medical information or pharmaceutical research only.
  - If I have any questions about the research process. I can contact Dr. Sansanee Neelawattanasuk, telephone number 085-000-9468, Department of Oral and Maxillofacial Surgery, Faculty of Dentistry Chiang Mai University, telephone 053-944456 (during official hours).
- I have read all the information and am willing to participate in the clinical research study.

Signature On behalf of Participant 5 (น.ส. อรพลินทร ทองเอก) 471 Date 08 Jan 2015 472 (Dr. Yanisa Naruenartwongsakul, D.D.S), Email: fai.fai.yanisa@gmail.com 473 I have explained the purpose of the research, the research methods, dangers or adverse reactions 474 or risks that may arise from the research, or from the medicine used Including the benefits that 475 476 will arise from thorough research. Let the participants in the research project named above know and have a good understanding. Ready to sign the consent document willingly. 477 James N Signature: 478 Date 08 Jan 2015 479 Researcher: Dr. Yanisa Naruenartwongsakul, D.D.S., Email: fai.fai.yanisa@gmail.com 480 481 Participant 6 (Code MF19) 482 I, น.ส. ระสิพภรณ์ กาฝากทอง age 19.9 years old, HN 6703379 Village No. ..... 483 Subdistrict...... District...... Province....... 484 read the details from the attached information sheet for research project participants. and I agree 485 to voluntarily participate in the said research project. 486 I have received a copy of the consent to participate in the research project that I signed and dated, 487 along with a document explaining information for research participants. This is before signing the 488 consent form to conduct this research. I was explained by the researcher about the purpose of the 489 490 research. The duration of the research, research methods, dangers or symptoms that may arise from the research, or from the medicine used Including the benefits that will arise from the research. 491 and guidelines for treatment by other methods in detail. I have had enough time and opportunity 492 493 to ask questions until I have a good understanding. The researcher answered various questions 494 willingly and without concealment until I was satisfied. - I am informed by the researcher that if there is any danger from such research. I will receive 495 medical treatment free of charge. 496 I have the right to terminate my participation in the research project at any time. You must 497 notify the reason, and termination of participation in this research It will not affect 498 499 treatment or other rights that I will continue to receive. - The researcher guarantees that my personal information will be kept secret, and will be 500 disclosed only with my consent. Other persons on behalf of the research sponsoring 501 502 company Human Research Ethics Committee. The Food and Drug Administration may be permitted to inspect and process my information. This must be done for the purpose of 503 verifying the accuracy of the information only. By agreeing to participate in this study, I 504 am giving consent to have my medical history reviewed. I understand that I have the right 505

506	to inspect or correct my personal data and can revoke my authorization to use my personal
507	data. This must be informed to the researcher.
508	- I am aware that the research information includes my medical information which is
509	anonymous. It will go through various processes such as collecting data. Recording
510	information in records and on computers, examining, analyzing, and reporting information
511	for academic purposes. Including future use of medical information or pharmaceutical
512	research only.
513	- If I have any questions about the research process. I can contact Dr. Sansanee
514	Neelawattanasuk, telephone number 085-000-9468, Department of Oral and Maxillofacial
515	Surgery, Faculty of Dentistry Chiang Mai University, telephone 053-944456 (during
516	official hours).
517	I have read all the information and am willing to participate in the clinical research study.
	General M
518	Signature On behalf of Participant 6 (น.ส. ระสิพภรณ์ กาฝากทอง)
519	Date 08 Jan 2015
520	(Dr. Yanisa Naruenartwongsakul, D.D.S., Email: fai.fai.yanisa@gmail.com
521	I have explained the purpose of the research, the research methods, dangers or adverse reactions
522	or risks that may arise from the research. or from the medicine used Including the benefits that
523	will arise from thorough research. Let the participants in the research project named above know
524	and have a good understanding. Ready to sign the consent document willingly.
525	Signature:   Signature:
526	Date 08 Jan 2015
527	Researcher: Dr. Yanisa Naruenartwongsakul, D.D.S., Email: fai.fai.yanisa@gmail.com
528	
529	Participant 7 (Code MF20)
530	I, น.ส. วนิชา ยาละ <b>age 23.6 years old, HN 6703661</b> Village No
531	Subdistrict District Province
532	read the details from the attached information sheet for research project participants. and I agree
533	to voluntarily participate in the said research project.
534	I have received a copy of the consent to participate in the research project that I signed and dated,
535	along with a document explaining information for research participants. This is before signing the
536	consent form to conduct this research. I was explained by the researcher about the purpose of the
537	research. The duration of the research, research methods, dangers or symptoms that may arise from
538	the research. or from the medicine used Including the benefits that will arise from the research.
539	and guidelines for treatment by other methods in detail. I have had enough time and opportunity

- to ask questions until I have a good understanding. The researcher answered various questions willingly and without concealment until I was satisfied.
  - I am informed by the researcher that if there is any danger from such research. I will receive medical treatment free of charge.
  - I have the right to terminate my participation in the research project at any time. You must notify the reason. and termination of participation in this research It will not affect treatment or other rights that I will continue to receive.
  - The researcher guarantees that my personal information will be kept secret. and will be disclosed only with my consent. Other persons on behalf of the research sponsoring company Human Research Ethics Committee. The Food and Drug Administration may be permitted to inspect and process my information. This must be done for the purpose of verifying the accuracy of the information only. By agreeing to participate in this study, I am giving consent to have my medical history reviewed. I understand that I have the right to inspect or correct my personal data and can revoke my authorization to use my personal data. This must be informed to the researcher.
  - I am aware that the research information includes my medical information which is anonymous. It will go through various processes such as collecting data. Recording information in records and on computers, examining, analyzing, and reporting information for academic purposes. Including future use of medical information or pharmaceutical research only.
  - If I have any questions about the research process. I can contact Dr. Sansanee Neelawattanasuk, telephone number 085-000-9468, Department of Oral and Maxillofacial Surgery, Faculty of Dentistry Chiang Mai University, telephone 053-944456 (during official hours).
  - I have read all the information and am willing to participate in the clinical research study.

On behalf of **Participant 7** (น.ส. วนิชา ยาละ) Signature 2 Date 08 Jan 2015 (Dr. Yanisa Naruenartwongsakul, D.D.S), Email: fai.fai.yanisa@gmail.com I have explained the purpose of the research, the research methods, dangers or adverse reactions or risks that may arise from the research, or from the medicine used Including the benefits that will arise from thorough research. Let the participants in the research project named above know and have a good understanding. Ready to sign the consent document willingly. Janaa N Signature:

Date 08 Jan 2015

Researcher: Dr. Yanisa Naruenartwongsakul, D.D.S., Email: fai.fai.yanisa@gmail.com

## Participant 8 (Code MF21)

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- Subdistrict...... District...... Province...... 578
- read the details from the attached information sheet for research project participants, and I agree 579
- 580 to voluntarily participate in the said research project.
- I have received a copy of the consent to participate in the research project that I signed and dated, 581
- along with a document explaining information for research participants. This is before signing the 582
- consent form to conduct this research. I was explained by the researcher about the purpose of the 583
- research. The duration of the research, research methods, dangers or symptoms that may arise from 584
- 585 the research, or from the medicine used Including the benefits that will arise from the research.
- 586 and guidelines for treatment by other methods in detail. I have had enough time and opportunity
- to ask questions until I have a good understanding. The researcher answered various questions 587
- willingly and without concealment until I was satisfied. 588
  - I am informed by the researcher that if there is any danger from such research. I will receive medical treatment free of charge.
  - I have the right to terminate my participation in the research project at any time. You must notify the reason, and termination of participation in this research It will not affect treatment or other rights that I will continue to receive.
  - The researcher guarantees that my personal information will be kept secret, and will be disclosed only with my consent. Other persons on behalf of the research sponsoring company Human Research Ethics Committee. The Food and Drug Administration may be permitted to inspect and process my information. This must be done for the purpose of verifying the accuracy of the information only. By agreeing to participate in this study, I am giving consent to have my medical history reviewed. I understand that I have the right to inspect or correct my personal data and can revoke my authorization to use my personal data. This must be informed to the researcher.
  - I am aware that the research information includes my medical information which is anonymous. It will go through various processes such as collecting data. Recording information in records and on computers, examining, analyzing, and reporting information for academic purposes. Including future use of medical information or pharmaceutical research only.
  - If I have any questions about the research process. I can contact Dr. Sansanee Neelawattanasuk, telephone number 085-000-9468, Department of Oral and Maxillofacial Surgery, Faculty of Dentistry Chiang Mai University, telephone 053-944456 (during official hours).
- I have read all the information and am willing to participate in the clinical research study. 611

612	Signature John N	On behalf of <b>Participant 8</b> (นาย สหรัฐ อิวชาวนา)
640	D + 00 L 2015	

613 Date 08 Jan 2015

(Dr. Yanisa Naruenartwongsakul, D.D.S), Email: fai.fai.yanisa@gmail.com 614 I have explained the purpose of the research, the research methods, dangers or adverse reactions 615 or risks that may arise from the research, or from the medicine used Including the benefits that 616 617 will arise from thorough research. Let the participants in the research project named above know 618 and have a good understanding. Ready to sign the consent document willingly. Januar N 619 Signature: 2 Date 08 Jan 2015 620 621 Researcher: Dr. Yanisa Naruenartwongsakul, D.D.S., Email: fai.fai.yanisa@gmail.com 622 Participant 9 (Code MF22) 623 I, นาย เกริกกรรชัย คุณาชารกุล age 23.5 years old, HN 6704031 Village No. ..... 624 Subdistrict...... District...... Province....... 625 read the details from the attached information sheet for research project participants, and I agree 626 627 to voluntarily participate in the said research project. I have received a copy of the consent to participate in the research project that I signed and dated, 628 along with a document explaining information for research participants. This is before signing the 629 consent form to conduct this research. I was explained by the researcher about the purpose of the 630 research. The duration of the research, research methods, dangers or symptoms that may arise from 631 the research, or from the medicine used Including the benefits that will arise from the research. 632 633 and guidelines for treatment by other methods in detail. I have had enough time and opportunity to ask questions until I have a good understanding. The researcher answered various questions 634 635 willingly and without concealment until I was satisfied. - I am informed by the researcher that if there is any danger from such research. I will receive 636 medical treatment free of charge. 637 - I have the right to terminate my participation in the research project at any time. You must 638 notify the reason, and termination of participation in this research It will not affect 639 treatment or other rights that I will continue to receive. 640 - The researcher guarantees that my personal information will be kept secret, and will be 641 disclosed only with my consent. Other persons on behalf of the research sponsoring 642 company Human Research Ethics Committee. The Food and Drug Administration may be 643 permitted to inspect and process my information. This must be done for the purpose of 644 645 verifying the accuracy of the information only. By agreeing to participate in this study, I 646 am giving consent to have my medical history reviewed. I understand that I have the right to inspect or correct my personal data and can revoke my authorization to use my personal 647 data. This must be informed to the researcher. 648

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- I am aware that the research information includes my medical information which is anonymous. It will go through various processes such as collecting data. Recording

651	information in records and on computers, examining, analyzing, and reporting information
652	for academic purposes. Including future use of medical information or pharmaceutical
653	research only.
654	- If I have any questions about the research process. I can contact Dr. Sansanee
655	Neelawattanasuk, telephone number 085-000-9468, Department of Oral and Maxillofacial
656	Surgery, Faculty of Dentistry Chiang Mai University, telephone 053-944456 (during
657	official hours).
658	I have read all the information and am willing to participate in the clinical research study.
659	Signature On behalf of Participant 9 (นาย เกริกกรรชัย คุณาชารกุล)
660	Date 08 Jan 2015
661	(Dr. Yanisa Naruenartwongsakul, D.D.S), Email: fai.fai.yanisa@gmail.com
662	I have explained the purpose of the research, the research methods, dangers or adverse reactions
663	or risks that may arise from the research. or from the medicine used Including the benefits that
664	will arise from thorough research. Let the participants in the research project named above know
665	and have a good understanding. Ready to sign the consent document willingly.
666	Signature: None M
667	Date 08 Jan 2015
669	Researcher: Dr. Yanisa Naruenartwongsakul, D.D.S., Email: fai.fai.yanisa@gmail.com
668	Researcher. Dr. Tanisa Natuenattwongsakur, D.D.S., Eman. <u>rai.rai.yamsa@gman.com</u>
669	
670	Participant 10 (Code MF23)
671	I, น.ส. ขวัญทิพย์ วรบุตร age 23.6 years old, <b>HN 6509153</b> Village No
672	Subdistrict District Province
673	read the details from the attached information sheet for research project participants. and I agree
674	to voluntarily participate in the said research project.
675	I have received a copy of the consent to participate in the research project that I signed and dated,
676	along with a document explaining information for research participants. This is before signing the
677	consent form to conduct this research. I was explained by the researcher about the purpose of the
678	research. The duration of the research, research methods, dangers or symptoms that may arise from
679	the research. or from the medicine used Including the benefits that will arise from the research.
680	and guidelines for treatment by other methods in detail. I have had enough time and opportunity
681	to ask questions until I have a good understanding. The researcher answered various questions
682	willingly and without concealment until I was satisfied.
683	- I am informed by the researcher that if there is any danger from such research. I will receive
684	medical treatment free of charge.

- I have the right to terminate my participation in the research project at any time. You must notify the reason. and termination of participation in this research It will not affect treatment or other rights that I will continue to receive.
  - The researcher guarantees that my personal information will be kept secret. and will be disclosed only with my consent. Other persons on behalf of the research sponsoring company Human Research Ethics Committee. The Food and Drug Administration may be permitted to inspect and process my information. This must be done for the purpose of verifying the accuracy of the information only. By agreeing to participate in this study, I am giving consent to have my medical history reviewed. I understand that I have the right to inspect or correct my personal data and can revoke my authorization to use my personal data. This must be informed to the researcher.
  - I am aware that the research information includes my medical information which is anonymous. It will go through various processes such as collecting data. Recording information in records and on computers, examining, analyzing, and reporting information for academic purposes. Including future use of medical information or pharmaceutical research only.
  - If I have any questions about the research process. I can contact Dr. Sansanee Neelawattanasuk, telephone number 085-000-9468, Department of Oral and Maxillofacial Surgery, Faculty of Dentistry Chiang Mai University, telephone 053-944456 (during official hours).
  - I have read all the information and am willing to participate in the clinical research study.

706 Signature On behalf of Participant 10 (น.ส. ขวัญทิพย์ วรบุตร)

Date 12 Jan 2015

(Dr. Yanisa Naruenartwongsakul, D.D.S), Email: fai.fai.yanisa@gmail.com

I have explained the purpose of the research, the research methods, dangers or adverse reactions

or risks that may arise from the research, or from the medicine used Including the benefits that

will arise from thorough research. Let the participants in the research project named above know

and have a good understanding. Ready to sign the consent document willingly.

713 Signature:

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714 Date 12 Jan 2015

Researcher: Dr. Yanisa Naruenartwongsakul, D.D.S., Email: fai.fai.yanisa@gmail.com

717 **Participant 11 (Code MF24)** 

719 Subdistrict District Province ....

- read the details from the attached information sheet for research project participants. and I agree to voluntarily participate in the said research project.
- I have received a copy of the consent to participate in the research project that I signed and dated, along with a document explaining information for research participants. This is before signing the consent form to conduct this research. I was explained by the researcher about the purpose of the research. The duration of the research, research methods, dangers or symptoms that may arise from the research, or from the medicine used Including the benefits that will arise from the research. and guidelines for treatment by other methods in detail. I have had enough time and opportunity to ask questions until I have a good understanding. The researcher answered various questions willingly and without concealment until I was satisfied.

- I am informed by the researcher that if there is any danger from such research. I will receive medical treatment free of charge.
- I have the right to terminate my participation in the research project at any time. You must notify the reason. and termination of participation in this research It will not affect treatment or other rights that I will continue to receive.
- The researcher guarantees that my personal information will be kept secret. and will be disclosed only with my consent. Other persons on behalf of the research sponsoring company Human Research Ethics Committee. The Food and Drug Administration may be permitted to inspect and process my information. This must be done for the purpose of verifying the accuracy of the information only. By agreeing to participate in this study, I am giving consent to have my medical history reviewed. I understand that I have the right to inspect or correct my personal data and can revoke my authorization to use my personal data. This must be informed to the researcher.
- I am aware that the research information includes my medical information which is anonymous. It will go through various processes such as collecting data. Recording information in records and on computers, examining, analyzing, and reporting information for academic purposes. Including future use of medical information or pharmaceutical research only.
- If I have any questions about the research process. I can contact Dr. Sansanee Neelawattanasuk, telephone number 085-000-9468, Department of Oral and Maxillofacial Surgery, Faculty of Dentistry Chiang Mai University, telephone 053-944456 (during official hours).
- 752 I have read all the information and am willing to participate in the clinical research study.

753 Signature On behalf of **Participant 11** (น.ส. กันยารัตน์ ยะวัน)
754 Date 12 Jan 2015

(Dr. Yanisa Naruenartwongsakul, D.D.S), Email: fai.fai.yanisa@gmail.com
756 I have explained the purpose of the research, the research methods, dangers or adverse r

I have explained the purpose of the research, the research methods, dangers or adverse reactions or risks that may arise from the research, or from the medicine used Including the benefits that

will arise from thorough research. Let the participants in the research project named above know and have a good understanding. Ready to sign the consent document willingly.

760 Signature: Januar M

761 Date 12 Jan 2015

Researcher: Dr. Yanisa Naruenartwongsakul, D.D.S., Email: fai.fai.yanisa@gmail.com

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## Participant 12 (Code MF25)

- 765 I, น.ส. ยุพารัตน์ จุดเสน age 21.7 years old, HN 6609696 Village No. ......
- 766 Subdistrict...... District....... Province.......
- read the details from the attached information sheet for research project participants. and I agree
- to voluntarily participate in the said research project.
- I have received a copy of the consent to participate in the research project that I signed and dated,
- along with a document explaining information for research participants. This is before signing the
- consent form to conduct this research. I was explained by the researcher about the purpose of the
- research. The duration of the research, research methods, dangers or symptoms that may arise from
- the research, or from the medicine used Including the benefits that will arise from the research.
- and guidelines for treatment by other methods in detail. I have had enough time and opportunity
- to ask questions until I have a good understanding. The researcher answered various questions
- willingly and without concealment until I was satisfied.
  - I am informed by the researcher that if there is any danger from such research. I will receive medical treatment free of charge.
  - I have the right to terminate my participation in the research project at any time. You must notify the reason. and termination of participation in this research It will not affect treatment or other rights that I will continue to receive.
  - The researcher guarantees that my personal information will be kept secret. and will be disclosed only with my consent. Other persons on behalf of the research sponsoring company Human Research Ethics Committee. The Food and Drug Administration may be permitted to inspect and process my information. This must be done for the purpose of verifying the accuracy of the information only. By agreeing to participate in this study, I am giving consent to have my medical history reviewed. I understand that I have the right to inspect or correct my personal data and can revoke my authorization to use my personal data. This must be informed to the researcher.
  - I am aware that the research information includes my medical information which is anonymous. It will go through various processes such as collecting data. Recording information in records and on computers, examining, analyzing, and reporting information for academic purposes. Including future use of medical information or pharmaceutical research only.

- If I have any questions about the research process. I can contact Dr. Sansanee 795 Neelawattanasuk, telephone number 085-000-9468, Department of Oral and Maxillofacial 796 Surgery, Faculty of Dentistry Chiang Mai University, telephone 053-944456 (during 797 official hours). 798 799 I have read all the information and am willing to participate in the clinical research study. On behalf of Participant 12 (น.ส. ยูพารัตน์ อุตเสน) 800 Signature Date 12 Jan 2015 801 802 (Dr. Yanisa Naruenartwongsakul, D.D.S), Email: fai.fai.yanisa@gmail.com I have explained the purpose of the research, the research methods, dangers or adverse reactions 803 or risks that may arise from the research, or from the medicine used Including the benefits that 804 will arise from thorough research. Let the participants in the research project named above know 805 and have a good understanding. Ready to sign the consent document willingly. 806 Janar N Signature: 807 Date 12 Jan 2015 808 809 Researcher: Dr. Yanisa Naruenartwongsakul, D.D.S., Email: fai.fai.yanisa@gmail.com 810 811 Participant 13 (Code MF26) 812 Subdistrict...... District...... Province...... 813 814 read the details from the attached information sheet for research project participants, and I agree to voluntarily participate in the said research project. 815 816 I have received a copy of the consent to participate in the research project that I signed and dated, 817 along with a document explaining information for research participants. This is before signing the consent form to conduct this research. I was explained by the researcher about the purpose of the 818 research. The duration of the research, research methods, dangers or symptoms that may arise from 819 820 the research, or from the medicine used Including the benefits that will arise from the research. 821 and guidelines for treatment by other methods in detail. I have had enough time and opportunity 822 to ask questions until I have a good understanding. The researcher answered various questions willingly and without concealment until I was satisfied. 823 - I am informed by the researcher that if there is any danger from such research. I will receive 824 medical treatment free of charge. 825 826 - I have the right to terminate my participation in the research project at any time. You must 827 notify the reason, and termination of participation in this research It will not affect treatment or other rights that I will continue to receive. 828

- The researcher guarantees that my personal information will be kept secret, and will be 829 disclosed only with my consent. Other persons on behalf of the research sponsoring 830 company Human Research Ethics Committee. The Food and Drug Administration may be 831 permitted to inspect and process my information. This must be done for the purpose of 832 verifying the accuracy of the information only. By agreeing to participate in this study, I 833 am giving consent to have my medical history reviewed. I understand that I have the right 834 to inspect or correct my personal data and can revoke my authorization to use my personal 835 data. This must be informed to the researcher. 836 - I am aware that the research information includes my medical information which is 837 anonymous. It will go through various processes such as collecting data. Recording 838 information in records and on computers, examining, analyzing, and reporting information 839 for academic purposes. Including future use of medical information or pharmaceutical 840 841 research only. - If I have any questions about the research process. I can contact Dr. Sansanee 842 843 Neelawattanasuk, telephone number 085-000-9468, Department of Oral and Maxillofacial Surgery, Faculty of Dentistry Chiang Mai University, telephone 053-944456 (during 844 845 official hours). I have read all the information and am willing to participate in the clinical research study. 846 On behalf of Participant 13 (น.ส. ธชวรรณ เตชกาญจนารักษ์) Signature 847 Date 12 Jan 2015 848 (Dr. Yanisa Naruenartwongsakul, D.D.S), Email: fai.fai.yanisa@gmail.com 849 I have explained the purpose of the research, the research methods, dangers or adverse reactions 850 851 or risks that may arise from the research, or from the medicine used Including the benefits that will arise from thorough research. Let the participants in the research project named above know 852 and have a good understanding. Ready to sign the consent document willingly. 853 Janaa N Signature: 854 Date 12 Jan 2015 855 Researcher: Dr. Yanisa Naruenartwongsakul, D.D.S., Email: fai.fai.yanisa@gmail.com 856 857 Participant 14 (Code MF1) 858 I, นายณัฐดนัย ศิริแก้ว age 21.5 years old, HN 6304573 Village No. ..... 859 Subdistrict...... District...... Province...... 860 read the details from the attached information sheet for research project participants, and I agree 861

to voluntarily participate in the said research project.

I have received a copy of the consent to participate in the research project that I signed and dated, along with a document explaining information for research participants. This is before signing the consent form to conduct this research. I was explained by the researcher about the purpose of the research. The duration of the research, research methods, dangers or symptoms that may arise from the research. or from the medicine used Including the benefits that will arise from the research, and guidelines for treatment by other methods in detail. I have had enough time and opportunity to ask questions until I have a good understanding. The researcher answered various questions willingly and without concealment until I was satisfied.

- I am informed by the researcher that if there is any danger from such research. I will receive medical treatment free of charge.
- I have the right to terminate my participation in the research project at any time. You must notify the reason. and termination of participation in this research It will not affect treatment or other rights that I will continue to receive.
- The researcher guarantees that my personal information will be kept secret. and will be disclosed only with my consent. Other persons on behalf of the research sponsoring company Human Research Ethics Committee. The Food and Drug Administration may be permitted to inspect and process my information. This must be done for the purpose of verifying the accuracy of the information only. By agreeing to participate in this study, I am giving consent to have my medical history reviewed. I understand that I have the right to inspect or correct my personal data and can revoke my authorization to use my personal data. This must be informed to the researcher.
- I am aware that the research information includes my medical information which is anonymous. It will go through various processes such as collecting data. Recording information in records and on computers, examining, analyzing, and reporting information for academic purposes. Including future use of medical information or pharmaceutical research only.
- If I have any questions about the research process. I can contact Dr. Sansanee Neelawattanasuk, telephone number 085-000-9468, Department of Oral and Maxillofacial Surgery, Faculty of Dentistry Chiang Mai University, telephone 053-944456 (during official hours).
- I have read all the information and am willing to participate in the clinical research study.

Jaman N On behalf of **Participant 14** (นายณัฐดนัย ศิริแก้ว) Signature Date 15 Jan 2015 (Dr. Yanisa Naruenartwongsakul, D.D.S), Email: fai.fai.yanisa@gmail.com I have explained the purpose of the research, the research methods, dangers or adverse reactions or risks that may arise from the research, or from the medicine used Including the benefits that will arise from thorough research. Let the participants in the research project named above know and have a good understanding. Ready to sign the consent document willingly.

# Signature: Yenav M

902 Date 15 Jan 2015

903 Researcher: Dr. Yanisa Naruenartwongsakul, D.D.S., Email: fai.fai.yanisa@gmail.com

## Participant 15 (Code MF2)

906	เายดชวิชญ์ อนุศาลนนันท์ <b>age 21.9 years old, HN 6304449</b> Village No
907	Subdistrict Province
908	ead the details from the attached information sheet for research project participants. and I agree
909	o voluntarily participate in the said research project.
910	have received a copy of the consent to participate in the research project that I signed and date
911	long with a document explaining information for research participants. This is before signing the
912	consent form to conduct this research. I was explained by the researcher about the purpose of the
913	esearch. The duration of the research, research methods, dangers or symptoms that may arise from
914	he research, or from the medicine used Including the benefits that will arise from the research
915	and guidelines for treatment by other methods in detail. I have had enough time and opportunit
916	o ask questions until I have a good understanding. The researcher answered various question
917	villingly and without concealment until I was satisfied.
918	- I am informed by the researcher that if there is any danger from such research. I will receive

- I am informed by the researcher that if there is any danger from such research. I will receive medical treatment free of charge.
- I have the right to terminate my participation in the research project at any time. You must notify the reason. and termination of participation in this research It will not affect treatment or other rights that I will continue to receive.
- The researcher guarantees that my personal information will be kept secret. and will be disclosed only with my consent. Other persons on behalf of the research sponsoring company Human Research Ethics Committee. The Food and Drug Administration may be permitted to inspect and process my information. This must be done for the purpose of verifying the accuracy of the information only. By agreeing to participate in this study, I am giving consent to have my medical history reviewed. I understand that I have the right to inspect or correct my personal data and can revoke my authorization to use my personal data. This must be informed to the researcher.
- I am aware that the research information includes my medical information which is anonymous. It will go through various processes such as collecting data. Recording information in records and on computers, examining, analyzing, and reporting information for academic purposes. Including future use of medical information or pharmaceutical research only.
- If I have any questions about the research process. I can contact Dr. Sansanee Neelawattanasuk, telephone number 085-000-9468, Department of Oral and Maxillofacial

Surgery, Faculty of Dentistry Chiang Mai University, telephone 053-944456 (during 938 official hours). 939 I have read all the information and am willing to participate in the clinical research study. 940 Janaa N 941 Signature On behalf of Participant 15 (นายดชวิชญ์ อนุศาลนนั้นท์) 942 Date 15 Jan 2015 (Dr. Yanisa Naruenartwongsakul, D.D.S), Email: fai.fai.yanisa@gmail.com 943 I have explained the purpose of the research, the research methods, dangers or adverse reactions 944 or risks that may arise from the research, or from the medicine used Including the benefits that 945 946 will arise from thorough research. Let the participants in the research project named above know and have a good understanding. Ready to sign the consent document willingly. 947 Yourse N 948 Signature: Date 15 Jan 2015 949 Researcher: Dr. Yanisa Naruenartwongsakul, D.D.S., Email: fai.fai.yanisa@gmail.com 950 951 952 Participant 16 (Code MF27) 953 954 Subdistrict...... District...... Province....... read the details from the attached information sheet for research project participants, and I agree 955 to voluntarily participate in the said research project. 956 I have received a copy of the consent to participate in the research project that I signed and dated, 957 along with a document explaining information for research participants. This is before signing the 958 consent form to conduct this research. I was explained by the researcher about the purpose of the 959 research. The duration of the research, research methods, dangers or symptoms that may arise from 960 961 the research, or from the medicine used Including the benefits that will arise from the research. and guidelines for treatment by other methods in detail. I have had enough time and opportunity 962 to ask questions until I have a good understanding. The researcher answered various questions 963 964 willingly and without concealment until I was satisfied. 965 - I am informed by the researcher that if there is any danger from such research. I will receive medical treatment free of charge. 966 - I have the right to terminate my participation in the research project at any time. You must 967 notify the reason, and termination of participation in this research It will not affect 968 969 treatment or other rights that I will continue to receive. - The researcher guarantees that my personal information will be kept secret, and will be 970 disclosed only with my consent. Other persons on behalf of the research sponsoring 971 company Human Research Ethics Committee. The Food and Drug Administration may be 972

permitted to inspect and process my information. This must be done for the purpose of 973 verifying the accuracy of the information only. By agreeing to participate in this study, I 974 am giving consent to have my medical history reviewed. I understand that I have the right 975 to inspect or correct my personal data and can revoke my authorization to use my personal 976 977 data. This must be informed to the researcher. - I am aware that the research information includes my medical information which is 978 anonymous. It will go through various processes such as collecting data. Recording 979 information in records and on computers, examining, analyzing, and reporting information 980 981 for academic purposes. Including future use of medical information or pharmaceutical research only. 982 - If I have any questions about the research process. I can contact Dr. Sansanee 983 Neelawattanasuk, telephone number 085-000-9468, Department of Oral and Maxillofacial 984 985 Surgery, Faculty of Dentistry Chiang Mai University, telephone 053-944456 (during official hours). 986 I have read all the information and am willing to participate in the clinical research study. 987 Jaman N Signature On behalf of Participant 16 (นาย คุณานนต์ สายวงค์อินทร์) 988 Date 15 Jan 2015 989 990 (Dr. Yanisa Naruenartwongsakul, D.D.S), Email: fai.fai.yanisa@gmail.com 991 I have explained the purpose of the research, the research methods, dangers or adverse reactions or risks that may arise from the research, or from the medicine used Including the benefits that 992 993 will arise from thorough research. Let the participants in the research project named above know 994 and have a good understanding. Ready to sign the consent document willingly. Januar N Signature: 995 996 Date 15 Jan 2015 997 Researcher: Dr. Yanisa Naruenartwongsakul, D.D.S., Email: fai.fai.yanisa@gmail.com 998 Participant 17 (Code MF28) 999 I, นาย ยหรเวท รอดประยูร age 21.5 years old, HN 6700592 Village No. ..... 1000 Subdistrict...... District...... Province....... 1001 1002 read the details from the attached information sheet for research project participants, and I agree 1003 to voluntarily participate in the said research project. 1004 I have received a copy of the consent to participate in the research project that I signed and dated, 1005 along with a document explaining information for research participants. This is before signing the 1006 consent form to conduct this research. I was explained by the researcher about the purpose of the research. The duration of the research, research methods, dangers or symptoms that may arise from 1007

the research. or from the medicine used Including the benefits that will arise from the research. and guidelines for treatment by other methods in detail. I have had enough time and opportunity to ask questions until I have a good understanding. The researcher answered various questions willingly and without concealment until I was satisfied.

- I am informed by the researcher that if there is any danger from such research. I will receive medical treatment free of charge.
- I have the right to terminate my participation in the research project at any time. You must notify the reason. and termination of participation in this research It will not affect treatment or other rights that I will continue to receive.
- The researcher guarantees that my personal information will be kept secret. and will be disclosed only with my consent. Other persons on behalf of the research sponsoring company Human Research Ethics Committee. The Food and Drug Administration may be permitted to inspect and process my information. This must be done for the purpose of verifying the accuracy of the information only. By agreeing to participate in this study, I am giving consent to have my medical history reviewed. I understand that I have the right to inspect or correct my personal data and can revoke my authorization to use my personal data. This must be informed to the researcher.
- I am aware that the research information includes my medical information which is anonymous. It will go through various processes such as collecting data. Recording information in records and on computers, examining, analyzing, and reporting information for academic purposes. Including future use of medical information or pharmaceutical research only.
- If I have any questions about the research process. I can contact Dr. Sansanee Neelawattanasuk, telephone number 085-000-9468, Department of Oral and Maxillofacial Surgery, Faculty of Dentistry Chiang Mai University, telephone 053-944456 (during official hours).
- I have read all the information and am willing to participate in the clinical research study.

Januar N On behalf of Participant 17 (นาย ยหูรเวท รอดประยูร) Signature Date 15 Jan 2015 (Dr. Yanisa Naruenartwongsakul, D.D.S), Email: fai.fai.yanisa@gmail.com I have explained the purpose of the research, the research methods, dangers or adverse reactions or risks that may arise from the research, or from the medicine used Including the benefits that will arise from thorough research. Let the participants in the research project named above know and have a good understanding. Ready to sign the consent document willingly. Januar N Signature: 2 Date 15 Jan 2015

Researcher: Dr. Yanisa Naruenartwongsakul, D.D.S., Email: fai.fai.yanisa@gmail.com

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#### Participant 18 (Code MF3)

- 1048 Subdistrict District Province.
- read the details from the attached information sheet for research project participants. and I agree
- to voluntarily participate in the said research project.
- I have received a copy of the consent to participate in the research project that I signed and dated,
- along with a document explaining information for research participants. This is before signing the
- consent form to conduct this research. I was explained by the researcher about the purpose of the
- research. The duration of the research, research methods, dangers or symptoms that may arise from
- the research. or from the medicine used Including the benefits that will arise from the research.
- and guidelines for treatment by other methods in detail. I have had enough time and opportunity
- to sale questions will I have a good understanding. The researcher engaged various questions
- to ask questions until I have a good understanding. The researcher answered various questions
- willingly and without concealment until I was satisfied.
  - I am informed by the researcher that if there is any danger from such research. I will receive medical treatment free of charge.
  - I have the right to terminate my participation in the research project at any time. You must notify the reason. and termination of participation in this research It will not affect treatment or other rights that I will continue to receive.
  - The researcher guarantees that my personal information will be kept secret. and will be disclosed only with my consent. Other persons on behalf of the research sponsoring company Human Research Ethics Committee. The Food and Drug Administration may be permitted to inspect and process my information. This must be done for the purpose of verifying the accuracy of the information only. By agreeing to participate in this study, I am giving consent to have my medical history reviewed. I understand that I have the right to inspect or correct my personal data and can revoke my authorization to use my personal data. This must be informed to the researcher.
  - I am aware that the research information includes my medical information which is anonymous. It will go through various processes such as collecting data. Recording information in records and on computers, examining, analyzing, and reporting information for academic purposes. Including future use of medical information or pharmaceutical research only.
  - If I have any questions about the research process. I can contact Dr. Sansanee Neelawattanasuk, telephone number 085-000-9468, Department of Oral and Maxillofacial Surgery, Faculty of Dentistry Chiang Mai University, telephone 053-944456 (during official hours).
- I have read all the information and am willing to participate in the clinical research study.

Signature On behalf of Participant 18 (นายธนพร แหทรัพย์)

Date 15 Jan 2015 1083 (Dr. Yanisa Naruenartwongsakul, D.D.S), Email: fai.fai.yanisa@gmail.com 1084 I have explained the purpose of the research, the research methods, dangers or adverse reactions 1085 or risks that may arise from the research, or from the medicine used Including the benefits that 1086 1087 will arise from thorough research. Let the participants in the research project named above know and have a good understanding. Ready to sign the consent document willingly. 1088 Janan N Signature: 2 1089 1090 Date 15 Jan 2015 Researcher: Dr. Yanisa Naruenartwongsakul, D.D.S., Email: fai.fai.yanisa@gmail.com 1091 1092 Participant 19 (Code MF4) 1093 I, น.ส. ปรารถนา เกษณา age 20.8 years old, HN 6304676 Village No. ..... 1094 1095 Subdistrict...... District...... Province....... 1096 read the details from the attached information sheet for research project participants, and I agree 1097 to voluntarily participate in the said research project. I have received a copy of the consent to participate in the research project that I signed and dated, 1098 along with a document explaining information for research participants. This is before signing the 1099 consent form to conduct this research. I was explained by the researcher about the purpose of the 1100 research. The duration of the research, research methods, dangers or symptoms that may arise from 1101 1102 the research, or from the medicine used Including the benefits that will arise from the research. and guidelines for treatment by other methods in detail. I have had enough time and opportunity 1103 to ask questions until I have a good understanding. The researcher answered various questions 1104 willingly and without concealment until I was satisfied. 1105 - I am informed by the researcher that if there is any danger from such research. I will receive 1106 medical treatment free of charge. 1107 - I have the right to terminate my participation in the research project at any time. You must 1108 notify the reason, and termination of participation in this research It will not affect 1109 1110 treatment or other rights that I will continue to receive. The researcher guarantees that my personal information will be kept secret, and will be 1111 disclosed only with my consent. Other persons on behalf of the research sponsoring 1112 company Human Research Ethics Committee. The Food and Drug Administration may be 1113 1114 permitted to inspect and process my information. This must be done for the purpose of 1115 verifying the accuracy of the information only. By agreeing to participate in this study, I am giving consent to have my medical history reviewed. I understand that I have the right 1116 to inspect or correct my personal data and can revoke my authorization to use my personal 1117 1118 data. This must be informed to the researcher.

1119	- I am aware that the research information includes my medical information which is
1120	anonymous. It will go through various processes such as collecting data. Recording
1121	information in records and on computers, examining, analyzing, and reporting information
1122	for academic purposes. Including future use of medical information or pharmaceutical
1123	research only.
1124	- If I have any questions about the research process. I can contact Dr. Sansanee
1125	Neelawattanasuk, telephone number 085-000-9468, Department of Oral and Maxillofacial
1126	Surgery, Faculty of Dentistry Chiang Mai University, telephone 053-944456 (during
1127	official hours).
1128	I have read all the information and am willing to participate in the clinical research study.
	Garage N
1129	Signature On behalf of Participant 19 (น.ส. ปรารถนา เกษณา)
	<u> </u>
1130	Date 15 Jan 2015
1131	(Dr. Yanisa Naruenartwongsakul, D.D.S), Email: fai.fai.yanisa@gmail.com
1132	I have explained the purpose of the research, the research methods, dangers or adverse reactions
1133	or risks that may arise from the research. or from the medicine used Including the benefits that will
1134	arise from thorough research. Let the participants in the research project named above know and
1135	have a good understanding. Ready to sign the consent document willingly.
1126	Signature. Venue N
1136	Signature: Signature:
1137	Date 15 Jan 2015
1138	Researcher: Dr. Yanisa Naruenartwongsakul, D.D.S., Email: fai.fai.yanisa@gmail.com
1136	Researcher. Dr. Tallisa Natuellartwoligsakur, D.D.S., Ellian. Idi. Idi. yallisa egilian.com
1139	
1140	Participant 20 (Code MF5)
1140	1 at ticipant 20 (Code Wifs)
1141	I, ธัญวิทูร เพื่อนสกุล age 25 years old, HN 6304801 Village No
1142	Subdistrict District Province
1143	read the details from the attached information sheet for research project participants. and I agree
1144	to voluntarily participate in the said research project.
1145	I have received a copy of the consent to participate in the research project that I signed and dated,
1146	along with a document explaining information for research participants. This is before signing the
1147	consent form to conduct this research. I was explained by the researcher about the purpose of the
1148	research. The duration of the research, research methods, dangers or symptoms that may arise from
1149	the research. or from the medicine used Including the benefits that will arise from the research.
1150	and guidelines for treatment by other methods in detail. I have had enough time and opportunity
1151	to ask questions until I have a good understanding. The researcher answered various questions
1152	willingly and without concealment until I was satisfied.

- I am informed by the researcher that if there is any danger from such research. I will receive medical treatment free of charge.
  - I have the right to terminate my participation in the research project at any time. You must notify the reason, and termination of participation in this research It will not affect treatment or other rights that I will continue to receive.
  - The researcher guarantees that my personal information will be kept secret. and will be disclosed only with my consent. Other persons on behalf of the research sponsoring company Human Research Ethics Committee. The Food and Drug Administration may be permitted to inspect and process my information. This must be done for the purpose of verifying the accuracy of the information only. By agreeing to participate in this study, I am giving consent to have my medical history reviewed. I understand that I have the right to inspect or correct my personal data and can revoke my authorization to use my personal data. This must be informed to the researcher.
  - I am aware that the research information includes my medical information which is anonymous. It will go through various processes such as collecting data. Recording information in records and on computers, examining, analyzing, and reporting information for academic purposes. Including future use of medical information or pharmaceutical research only.
  - If I have any questions about the research process. I can contact Dr. Sansanee Neelawattanasuk, telephone number 085-000-9468, Department of Oral and Maxillofacial Surgery, Faculty of Dentistry Chiang Mai University, telephone 053-944456 (during official hours).
- I have read all the information and am willing to participate in the clinical research study.

1176 Signature On behalf of Participant 20 (ชัญวิทูร เชื่อนสกุล)

1177 Date 15 Jan 2015

1178 (Dr. Yanisa Naruenartwongsakul, D.D.S), Email: fai.fai.yanisa@gmail.com
1179 I have explained the purpose of the research, the research methods, dangers or adverse reactions
1180 or risks that may arise from the research. or from the medicine used Including the benefits that will
1181 arise from thorough research. Let the participants in the research project named above know and
1182 have a good understanding. Ready to sign the consent document willingly.

Yours N

1183 Signature:

Date 15 Jan 2015

1185 Researcher: Dr. Yanisa Naruenartwongsakul, D.D.S., Email: fai.fai.yanisa@gmail.com

**Participant 21 (Code MF6)** 

1188 <mark>I,</mark>	นางสาวสุพัตรา กร	รเกษ age 20.8 years old,	<b>HN 6304793</b> Village No.	
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1189 Subdistrict...... District....... Province.......

read the details from the attached information sheet for research project participants. and I agree

to voluntarily participate in the said research project.

- I have received a copy of the consent to participate in the research project that I signed and dated, along with a document explaining information for research participants. This is before signing the consent form to conduct this research. I was explained by the researcher about the purpose of the research. The duration of the research, research methods, dangers or symptoms that may arise from the research. or from the medicine used Including the benefits that will arise from the research. and guidelines for treatment by other methods in detail. I have had enough time and opportunity to ask questions until I have a good understanding. The researcher answered various questions willingly and without concealment until I was satisfied.
  - I am informed by the researcher that if there is any danger from such research. I will receive medical treatment free of charge.
  - I have the right to terminate my participation in the research project at any time. You must notify the reason, and termination of participation in this research It will not affect treatment or other rights that I will continue to receive.
  - The researcher guarantees that my personal information will be kept secret. and will be disclosed only with my consent. Other persons on behalf of the research sponsoring company Human Research Ethics Committee. The Food and Drug Administration may be permitted to inspect and process my information. This must be done for the purpose of verifying the accuracy of the information only. By agreeing to participate in this study, I am giving consent to have my medical history reviewed. I understand that I have the right to inspect or correct my personal data and can revoke my authorization to use my personal data. This must be informed to the researcher.
  - I am aware that the research information includes my medical information which is anonymous. It will go through various processes such as collecting data. Recording information in records and on computers, examining, analyzing, and reporting information for academic purposes. Including future use of medical information or pharmaceutical research only.
  - If I have any questions about the research process. I can contact Dr. Sansanee Neelawattanasuk, telephone number 085-000-9468, Department of Oral and Maxillofacial Surgery, Faculty of Dentistry Chiang Mai University, telephone 053-944456 (during official hours).
- I have read all the information and am willing to participate in the clinical research study.

1223	Signature	Jonan N	On behalf of <b>Participant 21</b> (นางฮาวสุพัตรา กรรเกษ)
1224		Date 09/09/20	<mark>)16</mark>

(Dr. Yanisa Naruenartwongsakul, D.D.S), Email: fai.fai.vanisa@gmail.com 1225 I have explained the purpose of the research, the research methods, dangers or adverse reactions 1226 or risks that may arise from the research, or from the medicine used Including the benefits that 1227 will arise from thorough research. Let the participants in the research project named above know 1228 1229 and have a good understanding. Ready to sign the consent document willingly. Janar N 1230 Signature: 2 Date 09/09/2016 1231 1232 Researcher: Dr. Yanisa Naruenartwongsakul, D.D.S., Email: fai.fai.yanisa@gmail.com 1233 1234 Participant 22 (Code MF7) 1235 Subdistrict..... District...... Province...... 1236 1237 read the details from the attached information sheet for research project participants, and I agree to voluntarily participate in the said research project. 1238 I have received a copy of the consent to participate in the research project that I signed and dated, 1239 along with a document explaining information for research participants. This is before signing the 1240 consent form to conduct this research. I was explained by the researcher about the purpose of the 1241 research. The duration of the research, research methods, dangers or symptoms that may arise from 1242 1243 the research, or from the medicine used Including the benefits that will arise from the research. 1244 and guidelines for treatment by other methods in detail. I have had enough time and opportunity 1245 to ask questions until I have a good understanding. The researcher answered various questions willingly and without concealment until I was satisfied. 1246 - I am informed by the researcher that if there is any danger from such research. I will receive 1247 medical treatment free of charge. 1248 - I have the right to terminate my participation in the research project at any time. You must 1249 notify the reason, and termination of participation in this research It will not affect 1250 treatment or other rights that I will continue to receive. 1251 - The researcher guarantees that my personal information will be kept secret, and will be 1252 1253 disclosed only with my consent. Other persons on behalf of the research sponsoring company Human Research Ethics Committee. The Food and Drug Administration may be 1254 permitted to inspect and process my information. This must be done for the purpose of 1255 verifying the accuracy of the information only. By agreeing to participate in this study, I 1256 am giving consent to have my medical history reviewed. I understand that I have the right 1257 1258 to inspect or correct my personal data and can revoke my authorization to use my personal data. This must be informed to the researcher. 1259 - I am aware that the research information includes my medical information which is 1260 anonymous. It will go through various processes such as collecting data. Recording 1261

information in records and on computers, examining, analyzing, and reporting information

1263	for academic purposes. Including future use of medical information or pharmaceutical
1264	research only.
1265	- If I have any questions about the research process. I can contact Dr. Sansanee
1266	Neelawattanasuk, telephone number 085-000-9468, Department of Oral and Maxillofacial
1267	Surgery, Faculty of Dentistry Chiang Mai University, telephone 053-944456 (during
1268	official hours).
1269	I have read all the information and am willing to participate in the clinical research study.
1270	Signature On behalf of <b>Participant 22</b> (นางธาวรวี ปาฟอง)
1271	Date 16/09/2016
1272	(Dr. Yanisa Naruenartwongsakul, D.D.S), Email: fai.fai.yanisa@gmail.com
1273	I have explained the purpose of the research, the research methods, dangers or adverse reactions
1274	or risks that may arise from the research. or from the medicine used Including the benefits that
1275	will arise from thorough research. Let the participants in the research project named above know
1276	and have a good understanding. Ready to sign the consent document willingly.
1277	Signature: Yourse M
1278	Date 16/09/2016
1279	Researcher: Dr. Yanisa Naruenartwongsakul, D.D.S., Email: fai.fai.yanisa@gmail.com
	<u> </u>
1280	
1281	Participant 23 (Code MF8)
1282	I, นางสาวพริสร ศรีอุดมเดชสกุล age 20.7 years old, HN 6343863 Village No
1283	Subdistrict District Province
1284	read the details from the attached information sheet for research project participants. and I agree
1285	to voluntarily participate in the said research project.
1286	I have received a copy of the consent to participate in the research project that I signed and dated,
1287	along with a document explaining information for research participants. This is before signing the
1288	consent form to conduct this research. I was explained by the researcher about the purpose of the
1289	research. The duration of the research, research methods, dangers or symptoms that may arise from
1290	the research. or from the medicine used Including the benefits that will arise from the research.
1291	and guidelines for treatment by other methods in detail. I have had enough time and opportunity
1292	to ask questions until I have a good understanding. The researcher answered various questions
1293	willingly and without concealment until I was satisfied.
1294	- I am informed by the researcher that if there is any danger from such research. I will receive
1295	medical treatment free of charge.

- I have the right to terminate my participation in the research project at any time. You must notify the reason. and termination of participation in this research It will not affect treatment or other rights that I will continue to receive.
  - The researcher guarantees that my personal information will be kept secret. and will be disclosed only with my consent. Other persons on behalf of the research sponsoring company Human Research Ethics Committee. The Food and Drug Administration may be permitted to inspect and process my information. This must be done for the purpose of verifying the accuracy of the information only. By agreeing to participate in this study, I am giving consent to have my medical history reviewed. I understand that I have the right to inspect or correct my personal data and can revoke my authorization to use my personal data. This must be informed to the researcher.
  - I am aware that the research information includes my medical information which is anonymous. It will go through various processes such as collecting data. Recording information in records and on computers, examining, analyzing, and reporting information for academic purposes. Including future use of medical information or pharmaceutical research only.
  - If I have any questions about the research process. I can contact Dr. Sansanee Neelawattanasuk, telephone number 085-000-9468, Department of Oral and Maxillofacial Surgery, Faculty of Dentistry Chiang Mai University, telephone 053-944456 (during official hours).
- I have read all the information and am willing to participate in the clinical research study.

1317 Signature On behalf of Participant 23 (นางสาวพริสร ศรีอุดมเดชสกุล)

1318 Date 23/09/2016

(Dr. Yanisa Naruenartwongsakul, D.D.S), Email: fai.fai.yanisa@gmail.com

I have explained the purpose of the research, the research methods, dangers or adverse reactions

or risks that may arise from the research, or from the medicine used Including the benefits that

will arise from thorough research. Let the participants in the research project named above know

and have a good understanding. Ready to sign the consent document willingly.

1324 Signature:

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1327

Date 23/09/2016

Janan N

1326 Researcher: Dr. Yanisa Naruenartwongsakul, D.D.S., Email: fai.fai.yanisa@gmail.com

1328 Participant 24 (Code MF9)

- read the details from the attached information sheet for research project participants. and I agree to voluntarily participate in the said research project.
- I have received a copy of the consent to participate in the research project that I signed and dated. along with a document explaining information for research participants. This is before signing the consent form to conduct this research. I was explained by the researcher about the purpose of the research. The duration of the research, research methods, dangers or symptoms that may arise from the research, or from the medicine used Including the benefits that will arise from the research. and guidelines for treatment by other methods in detail. I have had enough time and opportunity to ask questions until I have a good understanding. The researcher answered various questions willingly and without concealment until I was satisfied.

- I am informed by the researcher that if there is any danger from such research. I will receive medical treatment free of charge.
- I have the right to terminate my participation in the research project at any time. You must notify the reason. and termination of participation in this research It will not affect treatment or other rights that I will continue to receive.
- The researcher guarantees that my personal information will be kept secret. and will be disclosed only with my consent. Other persons on behalf of the research sponsoring company Human Research Ethics Committee. The Food and Drug Administration may be permitted to inspect and process my information. This must be done for the purpose of verifying the accuracy of the information only. By agreeing to participate in this study, I am giving consent to have my medical history reviewed. I understand that I have the right to inspect or correct my personal data and can revoke my authorization to use my personal data. This must be informed to the researcher.
- I am aware that the research information includes my medical information which is anonymous. It will go through various processes such as collecting data. Recording information in records and on computers, examining, analyzing, and reporting information for academic purposes. Including future use of medical information or pharmaceutical research only.
- If I have any questions about the research process. I can contact Dr. Sansanee Neelawattanasuk, telephone number 085-000-9468, Department of Oral and Maxillofacial Surgery, Faculty of Dentistry Chiang Mai University, telephone 053-944456 (during official hours).
- I have read all the information and am willing to participate in the clinical research study.

1364 Signature On behalf of Participant 24 (นางสาวรัชชา ทรัพย์ยิ่งวัฒนา)

1365 Date 23/09/2016

1366 (Dr. Yanisa Naruenartwongsakul, D.D.S), Email: fai.fai.yanisa@gmail.com

1367 I have explained the purpose of the research, the research methods, dangers or adverse reactions
1368 or risks that may arise from the research. or from the medicine used Including the benefits that

will arise from thorough research. Let the participants in the research project named above know

and have a good understanding. Ready to sign the consent document willingly.

1371 Signature:

1372 Date 23/09/2016

1373 Researcher: Dr. Yanisa Naruenartwongsakul, D.D.S., Email: fai.fai.yanisa@gmail.com

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## Participant 25 (Code MF10)

- 1376 I, นายภูวนาท จิมสน age 20.3 years old, HN 6400108 Village No.......
- 1377 Subdistrict District Province.
- read the details from the attached information sheet for research project participants, and I agree
- to voluntarily participate in the said research project.
- I have received a copy of the consent to participate in the research project that I signed and dated,
- along with a document explaining information for research participants. This is before signing the
- consent form to conduct this research. I was explained by the researcher about the purpose of the
- research. The duration of the research, research methods, dangers or symptoms that may arise from
- the research, or from the medicine used Including the benefits that will arise from the research.
- and guidelines for treatment by other methods in detail. I have had enough time and opportunity
- to ask questions until I have a good understanding. The researcher answered various questions
- willingly and without concealment until I was satisfied.
  - I am informed by the researcher that if there is any danger from such research. I will receive medical treatment free of charge.
  - I have the right to terminate my participation in the research project at any time. You must notify the reason, and termination of participation in this research It will not affect treatment or other rights that I will continue to receive.
  - The researcher guarantees that my personal information will be kept secret. and will be disclosed only with my consent. Other persons on behalf of the research sponsoring company Human Research Ethics Committee. The Food and Drug Administration may be permitted to inspect and process my information. This must be done for the purpose of verifying the accuracy of the information only. By agreeing to participate in this study, I am giving consent to have my medical history reviewed. I understand that I have the right to inspect or correct my personal data and can revoke my authorization to use my personal data. This must be informed to the researcher.
  - I am aware that the research information includes my medical information which is anonymous. It will go through various processes such as collecting data. Recording information in records and on computers, examining, analyzing, and reporting information for academic purposes. Including future use of medical information or pharmaceutical research only.

1406	- If I have any questions about the research process. I can contact Dr. Sansanee
1407	Neelawattanasuk, telephone number 085-000-9468, Department of Oral and Maxillofacial
1408	Surgery, Faculty of Dentistry Chiang Mai University, telephone 053-944456 (during
1409	official hours).
1410	I have read all the information and am willing to participate in the clinical research study.
1411	Signature On behalf of <b>Participant 25</b> (นายภูวนาท ฉิมสน)
1412	Date 23/09/2016
1413	(Dr. Yanisa Naruenartwongsakul, D.D.S), Email: fai.fai.yanisa@gmail.com
1414	I have explained the purpose of the research, the research methods, dangers or adverse reactions
1415	or risks that may arise from the research. or from the medicine used Including the benefits that
1416	will arise from thorough research. Let the participants in the research project named above know
1417	and have a good understanding. Ready to sign the consent document willingly.
1418	Signature:
1419	Date 23/09/2016
1420	Researcher: Dr. Yanisa Naruenartwongsakul, D.D.S., Email: fai.fai.yanisa@gmail.com
1421	
1422	Participant 26 (Code MF11)
1423	I, นางสาวสิชาพัชร์ ภูมิสุข age 22.6 years old, HN 6400610 Village No
1424	Subdistrict District Province
1425	read the details from the attached information sheet for research project participants. and I agree
1426	to voluntarily participate in the said research project.
1427	I have received a copy of the consent to participate in the research project that I signed and dated,
1428	along with a document explaining information for research participants. This is before signing the
1429	consent form to conduct this research. I was explained by the researcher about the purpose of the
1430	research. The duration of the research, research methods, dangers or symptoms that may arise from
1431	the research. or from the medicine used Including the benefits that will arise from the research.
1432	and guidelines for treatment by other methods in detail. I have had enough time and opportunity
1433	to ask questions until I have a good understanding. The researcher answered various questions
1434	willingly and without concealment until I was satisfied.
1435	- I am informed by the researcher that if there is any danger from such research. I will receive
1436	medical treatment free of charge.
1437	- I have the right to terminate my participation in the research project at any time. You must
1438	notify the reason. and termination of participation in this research It will not affect
1439	treatment or other rights that I will continue to receive.

- The researcher guarantees that my personal information will be kept secret, and will be 1440 disclosed only with my consent. Other persons on behalf of the research sponsoring 1441 company Human Research Ethics Committee. The Food and Drug Administration may be 1442 permitted to inspect and process my information. This must be done for the purpose of 1443 1444 verifying the accuracy of the information only. By agreeing to participate in this study, I 1445 am giving consent to have my medical history reviewed. I understand that I have the right to inspect or correct my personal data and can revoke my authorization to use my personal 1446 data. This must be informed to the researcher. 1447 1448
  - I am aware that the research information includes my medical information which is anonymous. It will go through various processes such as collecting data. Recording information in records and on computers, examining, analyzing, and reporting information for academic purposes. Including future use of medical information or pharmaceutical research only.
  - If I have any questions about the research process. I can contact Dr. Sansanee Neelawattanasuk, telephone number 085-000-9468, Department of Oral and Maxillofacial Surgery, Faculty of Dentistry Chiang Mai University, telephone 053-944456 (during official hours).
- I have read all the information and am willing to participate in the clinical research study.

1458 Signature On behalf of Participant 26 (นางฮาวสิชาพัชร์ ภูมิสุข)

1459 Date 30/09/2016

1460 (Dr. Yanisa Naruenartwongsakul, D.D.S), Email: fai.fai.yanisa@gmail.com
1461 I have explained the purpose of the research, the research methods, dangers or adverse reactions
1462 or risks that may arise from the research. or from the medicine used Including the benefits that will
1463 arise from thorough research. Let the participants in the research project named above know and
1464 have a good understanding. Ready to sign the consent document willingly.

1465 Signature: Vonav M

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1466 Date 30/09/2016

Researcher: Dr. Yanisa Naruenartwongsakul, D.D.S., Email: fai.fai.yanisa@gmail.com

1469 Participant 27 (Code MF12)

- 1470 I, นายพงษ์พันธ์ สอนสี age 22.9 years old, HN 6402157 Village No.
- 1471 Subdistrict District Province
- read the details from the attached information sheet for research project participants, and I agree
- to voluntarily participate in the said research project.

I have received a copy of the consent to participate in the research project that I signed and dated, along with a document explaining information for research participants. This is before signing the consent form to conduct this research. I was explained by the researcher about the purpose of the research. The duration of the research, research methods, dangers or symptoms that may arise from the research. or from the medicine used Including the benefits that will arise from the research. and guidelines for treatment by other methods in detail. I have had enough time and opportunity to ask questions until I have a good understanding. The researcher answered various questions willingly and without concealment until I was satisfied.

- I am informed by the researcher that if there is any danger from such research. I will receive medical treatment free of charge.
- I have the right to terminate my participation in the research project at any time. You must notify the reason. and termination of participation in this research It will not affect treatment or other rights that I will continue to receive.
- The researcher guarantees that my personal information will be kept secret. and will be disclosed only with my consent. Other persons on behalf of the research sponsoring company Human Research Ethics Committee. The Food and Drug Administration may be permitted to inspect and process my information. This must be done for the purpose of verifying the accuracy of the information only. By agreeing to participate in this study, I am giving consent to have my medical history reviewed. I understand that I have the right to inspect or correct my personal data and can revoke my authorization to use my personal data. This must be informed to the researcher.
- I am aware that the research information includes my medical information which is anonymous. It will go through various processes such as collecting data. Recording information in records and on computers, examining, analyzing, and reporting information for academic purposes. Including future use of medical information or pharmaceutical research only.
- If I have any questions about the research process. I can contact Dr. Sansanee Neelawattanasuk, telephone number 085-000-9468, Department of Oral and Maxillofacial Surgery, Faculty of Dentistry Chiang Mai University, telephone 053-944456 (during official hours).
- I have read all the information and am willing to participate in the clinical research study.

1505 Signature On behalf of Participant 27 (นายพงษ์พันธ์ สอนลี)

1506 Date 30/09/2016

1507 (Dr. Yanisa Naruenartwongsakul, D.D.S), Email: fai.fai.yanisa@gmail.com

1508 I have explained the purpose of the research, the research methods, dangers or adverse reactions
1509 or risks that may arise from the research. or from the medicine used Including the benefits that will

have a good understanding. Ready to sign the consent document willingly.

Jonan N

arise from thorough research. Let the participants in the research project named above know and

		Youran N
1512	Signature:	T.

1513 Date 30/09/2016

1514 Researcher: Dr. Yanisa Naruenartwongsakul, D.D.S., Email: fai.fai.yanisa@gmail.com

## Participant 28 (Code MF13)

1517	I, นายนพเก้า จุไรรัตน์พร age 18.3 years old, HN 6306024 Village No
1518	Subdistrict District Province
1519	read the details from the attached information sheet for research project participants. and I agree
1520	to voluntarily participate in the said research project.
1521	I have received a copy of the consent to participate in the research project that I signed and dated,
1522	along with a document explaining information for research participants. This is before signing the
1523	consent form to conduct this research. I was explained by the researcher about the purpose of the
1524	research. The duration of the research, research methods, dangers or symptoms that may arise from
1525	the research. or from the medicine used Including the benefits that will arise from the research.
1526	and guidelines for treatment by other methods in detail. I have had enough time and opportunity
1527	to ask questions until I have a good understanding. The researcher answered various questions
1528	willingly and without concealment until I was satisfied.
1529	- I am informed by the researcher that if there is any danger from such research. I will receive

- I am informed by the researcher that if there is any danger from such research. I will receive medical treatment free of charge.
- I have the right to terminate my participation in the research project at any time. You must notify the reason. and termination of participation in this research It will not affect treatment or other rights that I will continue to receive.
- The researcher guarantees that my personal information will be kept secret. and will be disclosed only with my consent. Other persons on behalf of the research sponsoring company Human Research Ethics Committee. The Food and Drug Administration may be permitted to inspect and process my information. This must be done for the purpose of verifying the accuracy of the information only. By agreeing to participate in this study, I am giving consent to have my medical history reviewed. I understand that I have the right to inspect or correct my personal data and can revoke my authorization to use my personal data. This must be informed to the researcher.
- I am aware that the research information includes my medical information which is anonymous. It will go through various processes such as collecting data. Recording information in records and on computers, examining, analyzing, and reporting information for academic purposes. Including future use of medical information or pharmaceutical research only.
- If I have any questions about the research process. I can contact Dr. Sansanee Neelawattanasuk, telephone number 085-000-9468, Department of Oral and Maxillofacial

1549	Surgery, Faculty of Dentistry Chiang Mai University, telephone 053-944456 (during
1550	official hours).
1551	I have read all the information and am willing to participate in the clinical research study.
1552	Signature On behalf of Participant 28 (นายนพเด้า จุไรรัตน์พร)
1553	Date 30/09/2016
1554	(Dr. Yanisa Naruenartwongsakul, D.D.S), Email: fai.fai.yanisa@gmail.com
1555	I have explained the purpose of the research, the research methods, dangers or adverse reactions
1556	or risks that may arise from the research. or from the medicine used Including the benefits that
1557	will arise from thorough research. Let the participants in the research project named above know
1558	and have a good understanding. Ready to sign the consent document willingly.
1559	Signature:
1560	Date 30/09/2016
1561	Researcher: Dr. Yanisa Naruenartwongsakul, D.D.S., Email: fai.fai.yanisa@gmail.com

## Research protocol: part 2

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## 1563 **Budget: Total** 85,500 Thai baht

No.	Items	Cost
1	Gauze sheet, cotton, antiseptic	12,000
2	Disposable dental care equipment	15,000
3	Needles and syringes	13,500
4	Bupivacaine and lidocaine	25,000
5	Epinephrine	12,000
6	Sterile normal saline solution	8,000
	Total	85,500

- Other support for the project: Residency Training Program in Oral and Maxillofacial Surgery, Faculty of Dentistry, Chiang Mai University supported disposable small equipment and consumable reagents
- 1567 Collaboration with other scientists or research institutions: No
- 1568 Links to other projects: No
- 1569 **Curriculum Vitae of investigators:** We have now provided the CV of all the investigators.
- 1570 Other research activities of the investigators: All research projects have been finished.
- 1571 Financing and insurance: No