

Lidocaine and epinephrine mixture relieves pain from impacted molar surgery

Submission date 27/09/2024	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 01/10/2024	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 17/01/2025	Condition category Oral Health	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Mandibular third molars (the teeth at the back of the lower jaw) typically erupt in humans between 18 and 24 years of age. Accordingly, the lower third molar will commonly become impacted (stuck in the gum) and will have to be removed. However, discomfort and adverse effects may occur following an impacted tooth extraction such as edema (swelling), numbness, and excessive bleeding. Pain is the most prevalent problem following impacted tooth extractions. Pain perception affects individuals differently. The pain experienced from dental extraction and dental anesthesia can produce different responses among patients.

Local anesthetic drugs such as lidocaine and mepivacaine are used to alleviate pain during surgery or dental work. However, certain side effects, including redness, swelling, itching, dizziness, drowsiness, nausea, and, rarely, severe allergic reactions, have been observed with lidocaine. Bupivacaine reduced pain after impacted tooth extraction but did not decrease analgesic drug intake. Furthermore, irrigation of the tooth socket with bupivacaine after removal of the impacted third molar could significantly reduce the discomfort of the patient when compared to normal saline (salt water) irrigation.

The aim of this study is to compare the analgesic effects of lidocaine and bupivacaine compared with normal saline solution irrigation in patients after surgical removal of mandibular third molars.

Who can participate?

Patients aged between 18 and 25 years with impacted third molars

What does the study involve?

Participants are randomly allocated to receive lidocaine or bupivacaine 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 and asked to respond to questionnaires at 2, 4, 6, and 8 hours. Another tooth was surgically extracted after 4 weeks and patients were monitored as they had been for the previous surgery.

What are the possible benefits and risks of participating?

Irrigation of lidocaine plus epinephrine could help reduce pain after wisdom tooth extraction /surgery in the early stages, even though the effect of the injected anesthesia is somewhat

reduced. In addition, the irrigation will allow the patients not to bite on gauze, which may be inconvenient to take painkillers such as paracetamol or/and ibuprofen. Moreover, this technique is very helpful for postoperative patients, especially in cases where there may be severe pain after surgery due to a difficult time-consuming operation with a high pain response. There may be a risk of a dry socket but the percentage is very low, and some patients may be allergic or hypersensitive to the epinephrine.

Where is the study run from?
Chiang Mai University (Thailand)

When is the study starting and how long is it expected to run for?
October 2014 to December 2019

Who is funding the study?
Chiang Mai University (Thailand)

Who is the main contact?
Assistant Professor Dr. Vuttinun Chatupos, vuttinunch@yahoo.co.th

Contact information

Type(s)
Public, Scientific, Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers

42/2016

Study information

Scientific Title

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

Study objectives

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

Ethics approval required

Ethics approval required

Ethics approval(s)

1. Approved 03/12/2014, Chiang Mai University (Faculty of Dentistry, Chiangmai, 50200, Thailand; +66 (0)53944445; anak.ia@cmu.ac.th), ref: 52/2014

2. Approved 24/08/2016, Chiang Mai University (Faculty of Dentistry, Chiangmai, 50200, Thailand; +66 (0)53944445; anak.ia@cmu.ac.th), ref: 52/2014

Study design

Randomized controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Dental clinic

Study type(s)

Treatment

Participant information sheet

See study outputs table

Health condition(s) or problem(s) studied

Impacted lower mandibular molars

Interventions

Participants were randomly divided by block randomization to receive 2% lidocaine or 0.5% bupivacaine 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 2, 4, 6, and 8 hours. Another tooth was surgically extracted after 4 weeks and patients were again monitored, as they had been for the previous surgery.

Intervention Type

Drug

Pharmaceutical study type(s)

Not Applicable

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Lidocaine, epinephrine

Primary outcome measure

1. Duration of surgery and postoperative irrigation volume of NSS or lidocaine plus epinephrine used, recorded after surgery
2. Pain is measured using the visual analogue score (VAS) at baseline, 24, 48 and 72 hours
3. Number of paracetamol consumed, recorded after surgery
4. VAS-aided assessment of pain measured in participants receiving bupivacaine or lidocaine at 2, 4, 6, and 8 hours post-operation

Secondary outcome measures

There are no secondary outcome measures

Overall study start date

01/10/2014

Completion date

31/12/2019

Eligibility

Key inclusion criteria

1. Aged between 18 and 25 years
2. Systemically deemed to be healthy
3. Orthodontically indicated for impacted lower third molar on both sides as depicted in panoramic radiographs
4. Non-allergic to amoxicillin and paracetamol
5. Had not previously experienced inflammation or infection of the teeth and gums around the lower molars before treatment

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Upper age limit

25 Years

Sex

Both

Target number of participants

34

Total final enrolment

34

Key exclusion criteria

1. History of neurological disorders
2. Allergies to lidocaine and bupivacaine
3. Received steroid medication

Date of first enrolment

01/10/2015

Date of final enrolment

30/09/2016

Locations**Countries of recruitment**

Thailand

Study participating centre**Chiang Mai University**

Out-Patient Department Number 4

Department of Oral and Maxillofacial Surgery

Faculty of Dentistry

Chiang Mai

Thailand

50200

Sponsor information**Organisation**

Chiang Mai University

Sponsor details

Department of Biochemistry
Faculty of Medicine
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Sponsor type

University/education

Website

<http://www.dent.cmu.ac.th/mdj/frontend/web/?r=site/viewdata&id=7>

ROR

<https://ror.org/05m2fq25>

Funder(s)**Funder type**

Government

Funder Name

National Research Council of Thailand

Alternative Name(s)

NRCT

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

Thailand

Funder Name

Chiang Mai University

Alternative Name(s)

Chiang Mai University, THAILAND, , , , CMU

Funding Body Type

Government organisation

Funding Body Subtype
Universities (academic only)

Location
Thailand

Results and Publications

Publication and dissemination plan
Planned publications in peer-reviewed journals

Intention to publish date
15/10/2024

Individual participant data (IPD) sharing plan
The dataset generated during and/or the current study will be available upon request from Professor Dr Somdet Srichairatanakool, PhD, somdet.s@cmu.ac.th

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version 2		01/10/2024	No	Yes
Protocol file	version 2		01/10/2024	No	No
Results article		17/12/2024	17/01/2025	Yes	No