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Lidocaine and epinephrine mixture relieves pain from impacted molar surgery

Submission date
27/09/2024

Recruitment status
No longer recruiting

Registration date
01/10/2024

Overall study status
Completed

Last Edited
17/01/2025

Condition category
Oral Health

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
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

Study type(s)
Treatment

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

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Lidocaine, epinephrine

Primary outcome(s)

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

Key secondary outcome(s))
There are no secondary outcome measures

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
25 years

Sex
All

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

ROR
https://ror.org/05m2fqn25

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

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?
Results article		17/12/2024	17/01/2025	Yes	No
Participant information sheet	version 2		01/10/2024	No	Yes
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Protocol file	version 2		01/10/2024	No	No