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Efficacy of intraligamentary anaesthetic injection in mandibular premolars/incisors extraction

Submission date
27/01/2023

Recruitment status
No longer recruiting

Registration date
27/01/2023

Overall study status
Completed

Last Edited
28/01/2025

Condition category
Oral Health

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Pain control is the foundation of successful dental patient management. A good injection technique is essential for consistent anesthesia. There are different techniques for anesthesia. For the mandibular incisors and premolars (lower teeth), we can use the inferior alveolar nerve block (IANB) technique, but a number of disadvantages have been shown to be associated with this technique it is also the most frustrating with the highest percentage of failure even when properly administered. One of the alternative anesthetic techniques that can be used is the periodontal ligament (PDL) anesthetic technique (also referred to as the intraligamentary injection technique) and the incisive nerve block technique. The aim of this study is to determine which anesthetic technique is more effective at reducing pain during mandibular exodontia (removal of teeth).

Who can participate?
Patients aged from 20 to 60 years attending an outpatient dental clinic at Qassim University Saudi Arabia undergoing tooth extractions (mandibular premolars and incisors)

What does the study involve?
Participants were divided randomly into two groups. The first group is given an incisive block before extraction and the other group is given an intraligmentary injection. The pain during injection and extraction will be assessed in both groups.

What are the possible benefits and risks of participating?
The benefit is to reduce the need to give nerve blocks to reduce the pain experienced by the patient during local anesthesia injection and extraction. There is no risk in participating in this study

Where is the study run from?
College of Dentistry, Qassim University (Saudi Arabia)

When is the study starting and how long is it expected to run for?
November 2018 to June 2019

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
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Contact information

Type(s)
Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
EA/6015/2018

Study information

Scientific Title
Anesthetic efficacy of intraligamentary injection compared to incisive nerve block using 3% mepivacaine in mandibular premolars/incisors extraction: a randomized clinical trial

Study objectives

The aim of the study is to compare the pain experienced during injection and extraction of mandibular premolars and incisors using the intraligamentary injection technique (ILI) and the incisive nerve block technique (INB)

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 10/12/2018, Qassim University College of Dentistry Dental Ethics Committee (Research Ethics Committee, Dental Research Center, Qassim University, 51452, P.O. 6700, Saudi Arabia; +966 (0)163801761; ethical.committee@qudent.org), ref: EA/6015/2018

Study design
Prospective randomized comparative clinical trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Pain during mandibular exodontia

Interventions
The randomisation process was two sealed envelopes with the two interventions and one of the dental auxiliaries was requested to deliver them to the participant and requested to choose one of them.

Two local anesthetic techniques were used for the extraction of mandibular incisor/premolars For each technique, a standard 27-gauge short needle was used which was loaded with 3% mepivacaine. A topical anesthetic was applied at the site of injection. For patients receiving the ILT, the needle was directed parallel to the long axis of the tooth and inserted till the depth of the gingival sulcus on the mesial and distal aspects of the root, buccal and lingual side. A dose of 0.2 mL of LA was given over 30 seconds.

For patients receiving INBT, the needle was directed on the mucobuccal fold just anterior to the mental foramen. The depth of penetration is 5 to 6 mm. A dose of 0.6 mL of LA (approximately one-third of a cartridge) solution was given over 30 seconds, and 0.3 ml LA solution was given as lingual infiltration. The patients were asked to assess the degree of pain during needle insertion using the pain assessment form while waiting for the anesthesia to take effect. The extraction was performed after the symptoms were evaluated. After the extraction, the patients were asked to assess the pain of the extraction using the same form.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)

3% mepivacaine

Primary outcome(s)
Pain experienced during injection measured using the Modified Dental Anxiety Scale (MDAS) questionnaire and visual analog scales (VAS)

Key secondary outcome(s))
Pain experienced during extraction measured using the Modified Dental Anxiety Scale (MDAS) questionnaire and visual analog scales (VAS)

Completion date
01/06/2019

Eligibility

Key inclusion criteria
1. Healthy patients
2. Exhibiting a full understanding of the given oral instructions
3. Caries or fractures in relation to mandibular premolars and incisors that were not restorable

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Sex
All

Total final enrolment
100

Key exclusion criteria
1. Patients with a malignant neoplasm, cardiac pacemaker, diabetes or epilepsy
2. Pregnancy
3. Presence of acute dentoalveolar infection, periodontally compromised teeth
4. Unwilling to participate in the study

Date of first enrolment
01/01/2019

Date of final enrolment
01/06/2019

Locations

Countries of recruitment

Saudi Arabia

Study participating centre
Qassim University
College of Dentistry
King AbdulAziz Road Mulaida
Buraidah
Saudi Arabia
51452

Sponsor information

Organisation
Qassim University

ROR
https://ror.org/01wsfe280

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analyzed during the current study will be published as a supplement to the results publication

IPD sharing plan summary
Published as a supplement to the results publication

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		17/01/2025	28/01/2025	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes