

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jul 2026

Evaluation of anesthetic efficacy of incisive nerve block with articaine 4% and epinephrine 1/200000 compared to inferior alveolar nerve block with lidocaine 2% and epinephrine 1/80000 during mandibular second premolar extraction

Protocol summary

Study aim

Evaluation of anesthetic efficacy of incisive nerve block with articaine 4% and epinephrine 1/200000 compared to inferior alveolar nerve block with lidocaine 2% and epinephrine 1/80000 during mandibular second premolar extraction

Design

A clinical trial with a parallel intervention group, double-blind, randomized, on 42 patients. The sampling method is random. Randomization is done using a table of random numbers.

Settings and conduct

Patients referred to the Faculty of Dentistry in Tabriz, who need the extraction of second premolar teeth on both sides of the lower jaw, will participate in the study. The extraction of the second premolar tooth on one side of the patient's jaw will be performed using the lidocaine lower block method. After a week, the second premolar tooth on the opposite side will be extracted with the articaine incisive block method. Three factors will be investigated: 1- time to reach anesthesia (lip anesthesia) 2- the need for repeated injection of anesthesia 3- measurement of pain level with visual scale Analogue Scale (VAS) immediately after extracting each tooth. Teeth extraction will be done in both stages by the same person and under the same conditions. The patient is aware of the type of treatment but does not know which side of the jaw will be used. The evaluating researcher will not know about the type of intervention performed.

Participants/Inclusion and exclusion criteria

Inclusion criteria: patients needing bilateral mandibular block injection to extract premolar teeth Exclusion criteria: sensitivity to anesthetics

Intervention groups

Intervention: Anesthesia with articaine 4% with epinephrine 1.200000 Control: Anesthesia with lidocaine

with epinephrine 1.80000

Main outcome variables

Time to reach complete anesthesia The need for additional anesthesia injection The amount of pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230128057259N1**

Registration date: **2023-02-14, 1401/11/25**

Registration timing: **registered_while_recruiting**

Last update: **2023-02-14, 1401/11/25**

Update count: **0**

Registration date

2023-02-14, 1401/11/25

Registrant information

Name

Mohammad Mokhtarvand

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-02-02, 1401/11/13

Expected recruitment end date

2023-02-20, 1401/12/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluation of anesthetic efficacy of incisive nerve block with articaine 4% and epinephrine 1/200000 compared to inferior alveolar nerve block with lidocaine 2% and epinephrine 1/80000 during mandibular second premolar extraction

Public title
The dental anesthetic effect of articaine compared to lidocaine

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
Consent to participate in the study
Absence of systemic problem
Exclusion criteria:
Allergy to anesthetics
Pregnant or lactating women

Age
No age limit

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **42**
More than 1 sample in each individual
Number of samples in each individual: **2**
One side of the jaw is used as control and the other side is used as intervention.

Randomization (investigator's opinion)
Randomized

Randomization description
Random sampling will be done among the patients referred to the Faculty of Dentistry in Tabriz who are eligible for the study. The randomization method is simple and its unit is individual. Our tool for randomizing a table of random numbers. These patients will have premolars for extraction (as similar as possible) on both posterior sides of the mandible. The right side of the first referring patient will be considered as the control (lidocaine), the left side as the case (articaine), and the opposite will be done in the second patient. Patients do not know the type of intervention on each jaw side.

Blinding (investigator's opinion)
Double blinded

Blinding description
This study is double-blind so the patients do not know about the type of intervention on each side of the jaw. The evaluating researcher will not know about the type

of intervention performed. Patients know the type of material but do not know which side of the jaw will be used.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Tabriz University of Medical Sciences
Street address
Research and Technology Vice-Chancellor, 3rd Floor, Central Building No. 2, Tabriz University of Medical Sciences, Golgasht St., Tabriz.
City
Tabriz
Province
East Azarbaijan
Postal code
5166614711
Approval date
2022-10-03, 1401/07/11
Ethics committee reference number
IR.TBZMED.REC.1401.590

Health conditions studied

1

Description of health condition studied
Dental problems

ICD-10 code
Z13.8

ICD-10 code description
Encounter for screening for other specified diseases and disorders

Primary outcomes

1

Description
Time to reach complete anesthesia

Timepoint
Immediately after the end of all injections

Method of measurement
Immediately after the end of all injections; The duration of lip numbness will be measured with the lip numbness index and by a stopwatch.

2

Description

The need for additional anesthesia injection

Timepoint

After starting the extraction

Method of measurement

After starting the extraction and in order to maintain complete anesthesia and painlessness of the patient during the tooth extraction, if necessary, an injection of supplementary anesthesia (pdl injection) will be performed. (Extract will not be performed until optimal anesthesia is achieved)

3

Description

The amount of pain

Timepoint

During tooth extraction

Method of measurement

Visual Analogue Scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Teeth will be numbed with incisive block anesthesia technique with articaine 4% along with epinephrine 1/200000 (dentacaine by Elixir company).

Category

Treatment - Other

2

Description

Intervention group: The tooth will be anesthetized by lower alveolar nerve block method with lidocaine 2% along with epinephrine 1/80000 (Prazocaine of Daropakhsh Company).

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Faculty of Dentistry, Tabriz

Full name of responsible person

Mohsen Hashemi

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Faculty of dentistry, Tabriz university of medical sciences, Golgasht st. Tabriz.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Soodabeh Kimyai

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Tabriz University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Mohsen Hashemi

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable