

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Jul 2026

Comparison of the success rate of two anesthetic techniques using lidocain 2% in mandibular first premolars with symptomatic irreversible pulpitis

Protocol summary

Study aim

Comparison of the success rate of two anesthetic techniques using lidocain 2% in mandibular first premolars with symptomatic irreversible pulpitis

Design

A clinical trial with a parallel intervention group, double-blind, randomized, on 90 patients. The sampling method is random. Randomization is done using a table of random numbers.

Settings and conduct

90 patients referred to the endodontics department of the Faculty of Dentistry in Tabriz, suffering from symptomatic irreversible pulpitis in the mandibular first premolar teeth, will be included in the study based on the inclusion criteria. Patients will be randomly divided into two groups. Anesthesia injection will be done by lidocaine 2% along with epinephrine 1:80000. In the first group, anesthesia will be injected by the inferior alveolar block method, and in the second group by the buccal infiltration method (0.9 cc Carpol) along with the periodontal ligament (0.9 cc Carpol). While creating the access hole and entering the pulp chamber and entering the root canal, the success rate of anesthesia will be evaluated by the Visual Analogue Scale (VAS). The data collector and the treatment provider do not know the type of patient group.

Participants/Inclusion and exclusion criteria

Inclusion: Patients with mandibular first premolar with symptomatic irreversible pulpitis. Average (55-144mm) and severe (115-170mm) vas criteria before treatment

Exclusion: patients using painkillers, anti-inflammatory or sedative drugs in the last 12 hours, failure to achieve lip numbness after 15 minutes of block injection

Intervention groups

Intervention 1: Inferior alveolar block anesthesia

Intervention 2: Anesthesia by buccal infiltration method along with periodontal ligament

Main outcome variables

The amount of pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230301057581N1**

Registration date: **2023-03-07, 1401/12/16**

Registration timing: **registered_while_recruiting**

Last update: **2023-03-07, 1401/12/16**

Update count: **0**

Registration date

2023-03-07, 1401/12/16

Registrant information

Name

Maryam Fereydoonzadeh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 41 3556 4586

Email address

maryamfereydoonzadeh1@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-03-05, 1401/12/14

Expected recruitment end date

2023-04-26, 1402/02/06

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Comparison of the success rate of two anesthetic techniques using lidocain 2% in mandibular first premolars with symptomatic irreversible pulpitis

Public title
The effect of types of dental anesthesia with lidocaine

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
No systemic diseases No facial paresthesia Not taking drugs that interfere with anesthesia Absence of periodontal problems in the second premolar region of the mandible
Exclusion criteria:
Patients with congenital anomalies and structural defects in premolar teeth Patients undergoing radiotherapy or chemotherapy Patients with an allergy to anesthetics Smoking patients

Age
From **18 years** old to **65 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Care provider
- Outcome assessor

Sample size
Target sample size: **90**

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 randomization is a table of random numbers. Based on this, the type of treatment is marked with code A (anesthetic injection by inferior alveolar block method) and B (buccal infiltration method) and placed inside the sealed envelopes. take Then the envelopes are placed in a bag and mixed. Then it is randomly selected from the bag and treatment is given to the patient by observing the code. None of the patients will be informed about the treatment of another patient.

Blinding (investigator's opinion)
Double blinded

Blinding description
This study is double-blind, and data collection will be done by a dental assistant without knowing the type of patient group. Also, anesthesia injection and root canal treatment will be performed by two different dentists without knowing each other's work.

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

Tabriz University of Medical Sciences, Golgasht St.,

City

Tabriz

Province

East Azarbaijan

Postal code

5166614711

Approval date

2023-02-06, 1401/11/17

Ethics committee reference number

IR.TBZMED.REC.1401.995

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

The amount of pain

Timepoint

During root canal treatment

Method of measurement

Visual Analogue Scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Anesthesia injection will be done by

lidocaine 2% along with epinephrine 1:80000. In this group, the first injection of anesthesia will be by the inferior alveolar block method.

Category

Treatment - Other

2**Description**

Intervention group: Anesthesia injection will be done by lidocaine 2% along with epinephrine 1:80000. In this group, the first anesthetic injection will be by buccal infiltration method (0.9 cc carpol) along with inside the periodontal ligament (0.9 cc carpol).

Category

Treatment - Other

Recruitment centers**1****Recruitment center****Name of recruitment center**

Faculty of Dentistry, Tabriz

Full name of responsible person

Nagin Ghasemi

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

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Full name of responsible person

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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

Nagin Ghasemi

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

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Latest degree

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Other areas of specialty/work

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Person responsible for updating data

Contact

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Other areas of specialty/work
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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

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable