

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Jul 2026

Comparison of success rate of inferior alveolar nerve block protocol in mandibular first molars with symptomatic irreversible pulpitis by Prilocain and Mepivacain local anaesthesia: A randomized control clinical trial

Protocol summary

Study aim

Comparing the efficacy of Prilocaine versus Mepivacaine in inferior alveolar nerve block among the patients with irreversible pulpitis of the first molar teeth

Design

Randomized, superiority, parallel-group, double-blinded trial with blinded outcome assessment. Randomization was carried out by Randlist software.

Settings and conduct

This study was carried out in the endodontics ward of Tabriz University of Medical Science, faculty of dentistry. Patients were stratified into two groups after obtaining informed consent. standard alveolar nerve block then performed using 2 cartridges of Mepivacaine in one group and 2 cartridges of Prilocaine_Felypressin in the other group. fifteen minutes following the injection patients were evaluated for thermal and electrical pulp sensibility tests. In case of the accurate aesthetic state, root canal treatment was started, and the patient was asked to discuss any discomfort using VAS. both patients and researchers (including the operator, evaluator, and analyzer) were unaware of grouping during this study.

Participants/Inclusion and exclusion criteria

Patients between 18 and 65 years with symptomatic irreversible pulpitis in the first molar were enrolled in this research regarding the inclusion and exclusion criteria of the study.

Intervention groups

1. Mepivacaine group: inferior alveolar nerve block was performed using mepivacaine in this group 2. Prilocaine group: inferior alveolar nerve block was performed using prilocaine in this group

Main outcome variables

level of anesthesia in inferior alveolar nerve block

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200607047680N1**

Registration date: **2020-06-18, 1399/03/29**

Registration timing: **retrospective**

Last update: **2020-06-18, 1399/03/29**

Update count: **0**

Registration date

2020-06-18, 1399/03/29

Registrant information

Name

Parisa Rostami

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 45 3372 8095

Email address

pariisa.rostami9013@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-01-21, 1398/11/01

Expected recruitment end date

2020-04-19, 1399/01/31

Actual recruitment start date

2020-01-21, 1398/11/01

Actual recruitment end date

2020-05-04, 1399/02/15

Trial completion date

2020-05-04, 1399/02/15

Scientific title

Comparison of success rate of inferior alveolar nerve block protocol in mandibular first molars with symptomatic irreversible pulpitis by Prilocain and Mepivacain local anaesthesia: A randomized control clinical trial

Public title

anesthetic effect of Perilocain versus Mepivacain in inferior alveolar nerve block

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients between 18 and 65 years Indication of Root Canal Treatment (RCT) on first molar tooth Normal periapical appearance Patient's consent to participate in the study Evidence of symptomatic irreversible pulpitis that shows a predominant pain in response to cold pulp sensibility test compared to the control teeth

Exclusion criteria:

History of allergy to anesthetic agents (of any kind) Use of painkillers within 6 hours prior to the procedure Use of any kind of medication with possible interaction with anesthetic agents Presence of any pathological lesions at the site of injection Previous history of facial trauma Presence of pathological pocket while probing Patients without response to cold pulp sensibility test Presence of periradicular pathology severe than PDL widening Patients with partial necrosis

Age

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

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **100**

Actual sample size reached: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study randomization performed by Datinf Randlist software using a simple random sampling method

Blinding (investigator's opinion)

Double blinded

Blinding description

In this double-blinded study, both patients and researchers were unaware of group stratification. Patients were kept blind about the fact that in which group they enrolled. Also, all used anesthetic agents were unlabeled and coded by a third party before use.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics committee of Tabriz University of Medical Science

Street address

Ethics committee office, Tabriz University of Medical Science, Golgasht Ave., Azadi Blv.

City

Tabriz

Province

East Azarbaijan

Postal code

5166614711

Approval date

2020-01-20, 1398/10/30

Ethics committee reference number

IR.TBZMED.REC.1398.1159

Health conditions studied

1

Description of health condition studied

Inferior alveolar nerve block

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Level of analgesia based on Visual Analog Scale

Timepoint

15 minutes after injection

Method of measurement

Visual Analog Scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Inferior alveolar nerve block performed by single-shot injection of 2 cartridges of 3% mepivacaine (manufactured by Inibsa Dental s.t.u co) using a standard syringe with 27G, 3.6 cm needle.

Category

Treatment - Drugs

2

Description

Intervention group: Intervention group: Inferior alveolar nerve block performed by single-shot injection of 2 cartridges of 3% prilocaine_felypressin 0/03IU (manufactured by DarouPakhsh Pharmaceutical MFG co) using a standard syringe with 27G, 3.6 cm needle.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Faculty of Dentistry of Tabriz University of Medical Science

Full name of responsible person

Mahsa Eskandarinezhad

Street address

faculty of dentistry, Daneshgah Ave.

City

Tabriz

Province

East Azarbaijan

Postal code

5166614711

Phone

+98 41 3335 5965

Fax

+98 41 3334 6977

Email

dent.fac@tbzmed.ac.ir

Web page address

<https://dentistryfac.tbzmed.ac.ir/>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Mozhgan Kachuii

Street address

Faculty of Dentistry, Daneshgah Ave.

City

Tabriz

Province

East Azarbaijan

Postal code

5166614711

Phone

+98 41 3334 0310

Email

dent.fac@tbzmed.ac.ir

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

Mahsa Eskandarinezhad

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

Street address

Endodontics department, faculty of dentistry, Daneshgah Ave.

City

Tabriz

Province

East Azarbaijan

Postal code

5166614711

Phone

+98 41 3335 5965

Email

Eskandarinezhadmahsa@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Mahsa Eskandarinezhad

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

Street address

Endodontics department, faculty of dentistry, Daneshgah Ave.

City

Tabriz

Province

East Azarbaijan

Postal code

5166614711

Phone

+98 41 3335 5965

Email

Eskandarinezhadmahsa@yahoo.com

Person responsible for updating data**Contact****Name of organization / entity**

Tabriz University of Medical Sciences

Full name of responsible person

Parisa Rostami

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Dentistry

Street address

Department of endodontics, faculty of dentistry,
Daneshgah Ave.

City

Tabriz

Province

East Azarbaijan

Postal code

5166614711

Phone

+98 41 3335 5965

Fax**Email**

pariisa.rostami9013@gmail.com

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

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Individual participant data that underlie the reported results after proper deidentification

When the data will become available and for how long

following publication under the policy of the publisher

To whom data/document is available

Researchers who provide a methodologically sound proposal

Under which criteria data/document could be used

to achieve aims in the approved proposal

From where data/document is obtainable

Requests should be proposed to Dr. M. Eskandarinezhad via sending an email to eskandarinezhadmahsa@yahoo.com.

What processes are involved for a request to access data/document

proposals should be directed to "eskandarinezhadmahsa@yahoo.com". To gain access data requestors will need to sign a data access agreement.

Comments