Clinical Trial Protocol
Iranian Registry of Clinical Trials

11 Jul 2026

Comparision of success rate of inferior alveolar nerve block protocol in mandibular first molars with symptomatic irriversible 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)

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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
Comparision of success rate of inferior alveolar nerve block protocol in mandibular first molars with symptomatic irriversible 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 firs 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

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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
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Full name of responsible person
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Sponsors / Funding sources

1

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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
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Associate professor
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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