Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of the success rate of different anesthesia protocols in mandibular first molars with symptomatic irreversible pulpitis using prilocain local anesthesia : A randomized control clinical trial

Protocol summary

Study aim

Comparison of the success rate of different anesthesia protocols in mandibular first molars with symptomatic irreversible pulpitis using prilocain anesthetic agent: A randomized control clinical trial

Design

Clinical trial with control group, community based and pragmatic, factorial group, double blinded, randomized

Settings and conduct

128 patients who will be referred to the Department of Endodontics of Tabriz dental faculty, who meet the inclusion criteria and who with irreversible pulpitis in first mandibular molars, will be selected and divided into four groups of 32 patients according to the protocol of injection. The groups will be coded and presented to the statistical analyzer. The analyst will not be aware of the type of technique. Anesthesia and providing an access cavity and recording pain will be done by different persons. The pain recorder will not be aware of the study technique.

Participants/Inclusion and exclusion criteria

Entry requirements: Systemically healthy patient؛ Subjects 18-65 years of age؛ No sensivity to prilocaine؛ No facial parastesia؛ The patient with mandibular first molar with symptomatic irriversible pulpitis. Conditions of failure to enter: Any illness that is unable to fill the informed consent form؛ Lack of vital tissue in the pulp chamber during access cavity preparation

Intervention groups

Group 1: Injection of IANB(Inferior alveolar nerve block) Group 2: Injection of IANB technique + intraligament injection Group 3:Injection of IANB + Buccal infiltration Group 4: Two injection of standard IANB

Main outcome variables

The amount of pain the patient has

General information

Reason for update

Acronym

IANB

IRCT registration information

IRCT registration number: **IRCT20101108005141N7**
Registration date: **2018-04-04, 1397/01/15**
Registration timing: **retrospective**

Last update: **2018-04-04, 1397/01/15**
Update count: **0**

Registration date

2018-04-04, 1397/01/15

Registrant information

Name

Shahriar Shahi

Name of organization / entity

Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 41133559659

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-01-09, 1396/10/19

Expected recruitment end date

2018-06-10, 1397/03/20

Actual recruitment start date

2016-11-30, 1395/09/10

Actual recruitment end date

2017-11-04, 1396/08/13

Trial completion date
empty

Scientific title
Comparison of the success rate of different anesthesia protocols in mandibular first molars with symptomatic irreversible pulpitis using prilocain local anesthesia : A randomized control clinical trial

Public title
The success rate of different anesthesia protocols in mandibular posterior teeth

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Subjects 18-65 years of age No sensitivity to anesthetic agent No facial parasthesia Do not use of any narcotic drug 6 hours before treatment Patient not to be pregnancy No history of truma Absence of pathologic pockets during probing Patient with mandibular first molar with symptomatic irriversible pulpitis Normal view of teeth in periapical region

Exclusion criteria:
Any patients have not inclusion criteria Any illness that is unable to fill the informed consent form Absence of vital pulp tissue in access cavity

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

Gender
Both

Phase
N/A

Groups that have been masked

- Care provider
- Outcome assessor
- Data analyser

Sample size
Target sample size: **128**
Actual sample size reached: **128**

Randomization (investigator's opinion)
Randomized

Randomization description
We will have 32 patients in each group (16 women and 16 men) who will be randomly assigned into four groups. The randomization unit is individual. A randomization tool will be performed with the Randlist software (each patient entering the study will be assigned a number from 1 to 64 (for male and female) as a code and according to the arrenged numbers in the software will be randomized into four groups. The person who randomizes wont be aware of how to study.

Blinding (investigator's opinion)
Double blinded

Blinding description
1. The groups will be coded and presented to the statistical analyzer and the analyst wont be aware of the type of technique. 2. Anesthetizing will be done by one person and providing an access cavity and recording pain will be done by another person. The pain recorder wont be aware of the study technique.

Placebo
Not used

Assignment
Factorial

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committe of Tabriz University of Medical Sciences

Street address
3rd floor, No2 Centeral Building , Tabriz University of Medical Sciences, ,Golgasht street

City
Tabriz

Province
East Azarbaijan

Postal code
5166614711

Approval date
2017-09-30, 1396/07/08

Ethics committee reference number
IR.TBZMED.REC.1396.1076

Health conditions studied

1

Description of health condition studied
Symptomatic irreversible pulpitis

ICD-10 code
K04.0

ICD-10 code description
Pulpitis

Primary outcomes

1

Description
The amount of pain

Timepoint
During access cavity preparation and entrance in to the pulp chamber and the root canal

Method of measurement
Using Visual Analog Scale

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group1:IANB(Inferior alveolar nerve block) standard injection using prilocaine 3% solution (Prilocaine, Felypressin 0.03 IU/Darou Pakhsh,Iran) will be done . After 15 minutes of block anesthesia and numbness of the lips, an infiltration on the buccal side of the affected tooth will be performed at a rate of 0.5 ml with a normal syringe with 27 gauge needle. After 5 minutes, the teeth will be isolated and the access cavity will be done.

Category
Treatment - Other

2

Description
Intervention group 2: After IANB injection and 15 minute timeout and anesthesia of the lips, intra-ligament injection with a special injection syringe and a short needle with 27 gauge will be done.Then, in the mesial and distal teeth, 0.2 ml of the solution will be injected and after 5 minutes the access cavity will be prepared.

Category
Treatment - Other

3

Description
Intervention group 3:After IANB injection and 15 minute timeout and anesthesia of the lips, second IANB injection will be done.and after 5 minutes the access cavity will be prepared.

Category
Treatment - Other

4

Description
Control group:In the control group, standard block injection using Prilocaine 3% solution (Prilocaine, Felypressin 0.03 IU/Darou Pakhsh,Iran) will be done . After 15 minutes and anesthesia of the lips, teeth will be isolated and access prepration will be done.

Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Tabriz University of Medical Sciences
Full name of responsible person
Shahriar Shahi
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research, Tabriz University of Medical Sciences
Full name of responsible person
Prof. Abolghasem Jouyban
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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
Vice chancellor for research, 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
Dental and Periodontal Research Center

Full name of responsible person
Shahriar Shahi
Position
Professor of Endodontics
Latest degree
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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
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
No - There is not 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
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Not applicable