

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 sensitivity to prilocaine:
No facial parasthesia: The patient with mandibular first molar with symptomatic irreversible 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)

Phone

+98 41133559659

Email address

shahis@tbzmed.ac.ir

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 aranged 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 Central 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 preparation 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

Street address

3rd floor, No 2 Central Building , Tabriz University of Medical Sciences, Golgasht St

City

Tabriz

Province

East Azarbaijan

Postal code

5166614711

Phone

+98 41 3335 5965

Fax

+98 41 3334 6977

Email

sshahriar32@gmail.com

Web page address

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

Street address

3rd floor, No. 2 Central Building , Tabriz University of Medical Sciences, Golgasht St

City

Tabriz

Province

East Azarbaijan

Postal code

5166614711

Phone

+98 41 3335 5365

Fax

+98 41 3334 6977

Email

sshahriar32@gmail.com

Web page address

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

Specialist

Other areas of specialty/work

Endodontics

Street address3rd floor, No. 2 Cental Building ,Tabriz University of
Medical Science,Golgasht St**City**

Tabriz

Province

East Azarbaijan

Postal code

5166614711

Phone

+98 41 3335 5965

Fax

+98 41 3334 6977

Email

sshahriar32@gmail.com

Web page address

sshahriar32@gmail.com

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

Tabriz University of Medical Sciences

Full name of responsible person

Shahriar Shahi

Position

Professor of Endodontics

Latest degree

Specialist

Other areas of specialty/work

Dentistry

Street address3rd floor, No.2 Central Building , Tabriz University of
Medical Science, Golgasht St**City**

Tabriz

Province

East Azarbaijan

Postal code

5166614711

Phone

+98 41 3335 5965

Fax

+98 41 3334 6977

Email

sshshriar32@gmail.com

Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Faculty of Dentistry

Full name of responsible person

Shahriar Shahi

Position

Professor of Endodontics

Latest degree

Specialist

Other areas of specialty/work

Dentistry

Street address3rd floor, No2 Central Building , Tabriz University of
Medical Sciences, Golgasht St**City**

Tabriz

Province

East Azarbaijan

Postal code

5166614711

Phone

+98 41 3335 5965

Fax

+98 41 3334 6977

Email**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 ReportUndecided - 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