Clinical Trial Protocol
Iranian Registry of Clinical Trials

01 Jul 2026

Comparison the success of inferior alveolar nerve block with intraligament or buccal infiltration in mandibular first molar with symptomatic irriversible pulpitis : A randomized control clinical trial

Protocol summary

Study aim

Comparison the success of inferior alveolar nerve block with intraligaman or buccal infiltration in mamdibular first molar with symptomatic irriversible pulpitis

Design

Clinical trials with community based and pragmatic control group, with factorial groups, blinded and randomized

Settings and conduct

96 patients who referred to the Department of Endodontics of Tabriz Dental School, who had the criteria defined in the study and whose first mandibular molars were marked with irreversible pulpitis, were selected and divided into three groups of 32 according to the protocol of injection. The groups will be coded to the statistical analyzer and the analyst is not aware of the type of technique. Anesthetizing by one person and providing an access cavity and recording pain will be done by another person. The pain recorder is not aware of the study technique.

Participants/Inclusion and exclusion criteria

Entry requirements: Systemically healthy patient؛ Subjects 18-65 years of age: No sensivity to epinephrin and articaine؛ No facial parastacidae؛ The patient with the 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 I: Injection of IANB (Inferior alveolar nerve block) Group II: Injection of IANB + Buccal Infiltration Group III: Injection of IANB + intra-ligament injection

Main outcome variables

The amount of pain the patient has

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20101108005141N6**
Registration date: **2018-02-03, 1396/11/14**
Registration timing: **registered_while_recruiting**

Last update: **2018-02-03, 1396/11/14**
Update count: **0**

Registration date

2018-02-03, 1396/11/14

Registrant information

Name
Shahriar Shahi
Name of organization / entity
Tabriz University of Medical Sciences
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Iran (Islamic Republic of)
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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

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Comparison the success of inferior alveolar nerve block with intraligament or buccal infiltration in mandibular first molar with symptomatic irriversible pulpitis : A randomized control clinical trial

Public title
the success of inferior alveolar nerve block with intraligament or buccal infiltration in mandibular posterior teeth

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Systemically healthy patient Subjects 18-65 years of age No sensivity to epinephrin and articaine No facial parastacidae Do not use any medication 6 hours before treatment Not taking any medication that interferes with numbness No pathoes in the areas of injection Patient not to be pregnant Absence of pathologic pockets during probing The patient with the first molar with symptomatic irriversible pulpitis

Exclusion criteria:
Any illness that is unable to fill the informed consent form history of trauma

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

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Investigator
- Data analyser

Sample size
Target sample size: **96**
Actual sample size reached: **96**

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 three 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 48 (for male and female) as a code and sorted according to the numbers and the software will be randomized into three groups. The person who randomizes is not aware of how to study.

Blinding (investigator's opinion)
Double blinded

Blinding description
1. The groups will be coded to the statistical analyzer and the analyst is not aware of the type of technique. 2. Anesthetizing by one person and providing an access cavity and recording pain will be done by another person. The pain recorder is not 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 committee tabriz university of medical science

Street address
Floor3- Centeral Building No2-Tabriz University of Medical Sciences- Golgasht St

City
Tabriz

Province
East Azarbaijan

Postal code
5166614711

Approval date
2017-09-27, 1396/07/05

Ethics committee reference number
IR.TBZMED.REC.1396.462

Health conditions studied

1

Description of health condition studied
pulp disease

ICD-10 code
ICD-XI

ICD-10 code description
Diseases of pulp and periapical tissues

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
Use Visual Analogue Scale

Secondary outcomes

empty

Intervention groups

1

Description
Control group: In the control group, standard block injection was performed using Articanin 4% solution (Artinibsa; Inibsa, Barcelona, Spain) with epinephrine 100000/1. After 15 minutes, the anesthetized teeth were isolated and the cavity was prepared and access prepration will be done.

Category
Treatment - Other

2

Description
Intervention group 1: Block standard injection is performed using Articaine 4% solution (Artinibsa; Inibsa, Barcelona, Spain) with an epinephrine of 100,000/1. 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

3

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 is injected and after 5 minutes the access cavity is prepared.

Category
Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Tabriz university of medical science dentistry faculty

Full name of responsible person
Dr Shahriar Shahi

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Floor3, Central Building No2, Tabriz University of Medical Sciences, Golgasht St

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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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Floor3, Centeral Building No.2, Tabriz University of Medical Sciences- Golgasht St

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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
Periodontal and dental research center

Full name of responsible person
Dr shahriar shahi

Position
Professor of Endodontics

Latest degree
Specialist

Other areas of specialty/work
Dentistry

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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