

# 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 irreversible pulpitis : A randomized control clinical trial

#### Protocol summary

##### Study aim

Comparison the success of inferior alveolar nerve block with intraligament or buccal infiltration in mandibular first molar with symptomatic irreversible 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 sensitivity to epinephrine and articaine: No facial parasthesia: The patient with the 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 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

##### 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

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 irreversible 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 sensitivity to epinephrine and articaine No facial parasthesia Do not use any medication 6 hours before treatment Not taking any medication that interferes with numbness No pathology in the areas of injection Patient not to be pregnant Absence of pathologic pockets during probing The patient with the first molar with symptomatic irreversible 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 analyst

### 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

Floor 3- Central Building No 2- 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 preparation will be done.

### Category

Treatment - Other

## 2

### Description

Intervention group 1: Block standard injection is performed using Articaïne 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

#### Street address

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

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5166614711

#### Phone

+98 41 3335 5965

#### Email

Sshahriar32@gmail.com

## 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, Central 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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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
Faculty of dentistry  
**Full name of responsible person**  
Dr shahriar shahi  
**Position**  
Professor of Endodontics  
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**Other areas of specialty/work**  
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## Person responsible for updating data

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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