

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### **Aneasthetic success of Articaine\Epinephrine with combination of Mannitol in comparison with Articaine\Epinephrine for inferior alveolar nerve block in patients with symptomatic irreversible pulpitis: A randomized controlled clinical trial**

#### **Protocol summary**

##### **Study aim**

Aneasthetic success of Articaine\Epinephrine with combination of Mannitol in comparison with Articaine\Epinephrine for inferior alveolar nerve block in patients with symptomatic irreversible pulpitis

##### **Design**

Two arm parallel group randomised trial with blinded postoperative care and outcome assessment

##### **Settings and conduct**

This study will be done on 124 patients who will be referred to the Department of Endodontics of Tabriz University of Medical Sciences. The patients who will have the inclusion criterias that explained in the study and also have the first mandibular molars with irreversible pulpitis, will be selected. They will be randomly divided into two groups (n=62 in each group) according to the protocol of injection. The groups will be coded and presented to the statistical analyzer and the analyst wont be aware of the type of injection. One person will do injection and another one will provide an access cavity and record pain. The pain recorder wont be aware of the technique of injectin.

##### **Participants/Inclusion and exclusion criteria**

inclusion criteria: Systemically healthy patients; Subjects 18-65 years of age; patients with no sensivity to Mannitol; The patients with mandibular first molar with symptomatic irriversible pulpitis. exclusion criteria: Teeth with periradicular pathosis; patients with no response to cold testing.

##### **Intervention groups**

Group one received IANB by using 1.8 mL Articaine with 1:200000 Epinephrine. Group two received IANB by using 3-ml formulation of 1.9 ml Articaine with 1:200000 epinephrine plus 1.1 mL of 0.5 mol/L Mannitol.

##### **Main outcome variables**

The patient's pain degree

#### **General information**

##### **Reason for update**

##### **Acronym**

IANB

##### **IRCT registration information**

IRCT registration number: **IRCT20180228038901N1**

Registration date: **2018-04-30, 1397/02/10**

Registration timing: **retrospective**

Last update: **2018-04-30, 1397/02/10**

Update count: **0**

##### **Registration date**

2018-04-30, 1397/02/10

##### **Registrant information**

##### **Name**

sahar shakouei

##### **Name of organization / entity**

##### **Country**

Iran (Islamic Republic of)

##### **Phone**

+98 41 3335 5965

##### **Email address**

shakoueis@tbzmed.ac.ir

##### **Recruitment status**

**Recruitment complete**

##### **Funding source**

##### **Expected recruitment start date**

2018-04-04, 1397/01/15

##### **Expected recruitment end date**

2018-06-20, 1397/03/30

##### **Actual recruitment start date**

2017-01-04, 1395/10/15

##### **Actual recruitment end date**

2018-03-12, 1396/12/21

**Trial completion date**

empty

**Scientific title**

Aneasthetic success of Articaine\Epinephrine with combination of Mannitol in comparison with Articaine\Epinephrine for inferior alveolar nerve block in patients with symptomatic irreversible pulpitis: A randomized controlled clinical trial

**Public title**

Efficacy of Mannitol on the success rate of anesthesia in mandibular posterior teeth

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

patients without relevant medical conditions patients older than 18 Patients not taking beta-blockers patients not being medicated with any opioids preoperatively patients without drug abusing No pregnant or nursing mothers Those without a contraindication for the use of Mannitol Those known not to be allergic to one of the study medications Those without orofacial infection

**Exclusion criteria:**

subjects with negative response to cold testing Teeth with periradicular disease(unlike a widened periodontal ligament)

**Age**

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

**Gender**

Both

**Phase**

3

**Groups that have been masked**

- Participant
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

**Sample size**

Target sample size: **124**

Actual sample size reached: **124**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

We will have 62 patients in each group (31 women and 31 men) who will be randomly assigned into two groups. The randomization unit will be individual and the randomization tool will be Randlist software. Each patient entering the study will be assigned a number from 1 to 62 (for male and female) as a special code and they will be randomly put into two groups according to sorted numbers which will be set by software. The person who will randomize will not be aware of how to study.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

Pulp condition realizing tests and injection by one person and providing an access cavity and recording pain will be done by another person.Groups data will be coded and

reported as A,B to analyzer,so the analyzer and pain recorder are not aware of the study technique.

**Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics committee 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**

2018-03-12, 1396/12/21

**Ethics committee reference number**

IR.TBZMED.REC.1396.1269

**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 group 1: IANB (Inferior alveolar nerve block) standard injection using Articaine 4% solution (DENTACAIN, Exir, Iran) will be done. After 15 minutes of block anesthesia and numbness of the lips, the teeth will be isolated and the access cavity will be done.

#### Category

Treatment - Other

### 2

#### Description

Intervention group 2: under sterile conditions, 1.9 mL of 4% Articaine with 1:200,000 epinephrine will be drawn from standard dental cartridges (DENTACAIN, Exir, Tehran, Iran) into a sterile 3-mL Luer-Lok disposable syringe (AVA, Tehran, Iran). 1.1 mL of 0.5 mol/L mannitol will be added to this syringe, which will be withdrawn from a 500-mL solution of a 20% supersaturated mannitol solution (American Regent Laboratories, Inc, Shirley, NY) by using a sterile disposable syringe. To mixing the solution the combined Articaine/mannitol formulation in the syringe will be then inverted 20 times. Before the mannitol be added to the syringe containing the Articaine with epinephrine, the 50-mL vial will be heated in a water bath (Teledyne Hanau, Buffalo, NY) to 80°C for 15 minutes to remove any crystals present in the supersaturated solution. A standard IAN block will be done by using a 27-gauge, 1½-inch needle (AVA, Tehran, Iran), enclosed to the Luer-Lok syringe.

#### Category

Treatment - Other

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Tabriz University of Medical Sciences

##### Full name of responsible person

Sahar Shakouei

##### 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

## 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

sshakouie@hotmail.com

#### 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

Sahar Shakouei

##### Position

Associate Professor of Endodontics

##### Latest degree

Specialist

##### Other areas of specialty/work

Endodontics

##### Street address

3rd 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**

sshakouie@hotmail.com

## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**

Faculty of Dentistry

**Full name of responsible person**

Sahar Shakouei

**Position**

Associate Professor of Endodontics

**Latest degree**

Specialist

**Other areas of specialty/work**

Dentistry

**Street address**

3rd 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**

sshakouie@hotmail.com

## Person responsible for updating data

**Contact**

**Name of organization / entity**

Faculty of Dentistry

**Full name of responsible person**

Sahar Shakouei

**Position**

Associate professor of Endodontics

**Latest degree**

Specialist

**Other areas of specialty/work**

Dentistry

**Street address**

3rd 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**

sshakouie@hotmail.com

## 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