

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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)

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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

sshakouie@hotmail.com

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Description

Intervention group1: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

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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

Sahar Shakouei

Position

Associate Professor of Endodontics

Latest degree

Specialist

Other areas of specialty/work

Endodontics

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Faculty of Dentistry

Full name of responsible person

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Position

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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