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 respone 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

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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 Centeral 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 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
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Sponsors / Funding sources

1

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Full name of responsible person
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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
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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