Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Comparative evaluation of anesthetic efficacy of 1.8 mL articaine and 3.6 mL of articaine for mental nerve block in mandibular premolars with irreversible pulpitis: A randomized clinical trial study

Protocol summary

Study aim

Determine success rate of 1.8 articaine 4% mental nerve block in mandibular premolar with irreversible pulpitis by age and gender Determine success rate of 3.6 articaine 4% mental nerve block in mandibular premolar with irreversible pulpitis by age and gender Comparison of success rate in all 2 groups under investigation

Design

Randomised, parallel group trial with blinded outcome assessment. Randomisation will be written on pieces of paper and kept in sealed envelopes

Settings and conduct

The study will be performed by 2 dentists in a private clinic in Rafsanjan. After the anesthesia injection, patients and the operator are unaware (double-blinded). Patients are instructed to report any pain at any stage of treatment in VAS form.

Participants/Inclusion and exclusion criteria

Healthy adult patients 18–60 years old having mandibular premolar tooth with symptomatic irreversible pulpitis and a normal periapical radiographic appearance

Intervention groups

In the 1st group, 1.8 ml of 4% articaine solution (one anesthetic cartridge three minutes apart), in the second group, 3.6 ml of 4% articaine solution (one anesthetic cartridge and three minutes later followed by a moking injection); 2-3 minutes after the anesthesia injection, the patient is asked about the numbness of the lower lip, and if the answer is negative, he is excluded the study, If the answer is positive, the tooth will be isolate by a rubberdam, the caries will be removed, the access cavity is prepared and instrumentation will be performed.

Main outcome variables

Pain rate by Visual Analogue Scale form

General information

Reason for update

Acronym

MINB

IRCT registration information

IRCT registration number: **IRCT20210515051306N2**
Registration date: **2023-04-24, 1402/02/04**
Registration timing: **retrospective**

Last update: **2023-04-24, 1402/02/04**
Update count: **0**

Registration date

2023-04-24, 1402/02/04

Registrant information

Name

Ramin Abazarpoor

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 34 3424 2322

Email address

abazarpoor@rums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-12-01, 1401/09/10

Expected recruitment end date

2023-03-16, 1401/12/25

Actual recruitment start date

2022-12-27, 1401/10/06

Actual recruitment end date

2023-04-04, 1402/01/15

Trial completion date

2023-04-04, 1402/01/15

Scientific title
Comparative evaluation of anesthetic efficacy of 1.8 mL articaine and 3.6 mL of articaine for mental nerve block in mandibular premolars with irreversible pulpitis: A randomized clinical trial study

Public title
Anesthetic efficacy of two different volumes of articaine for mental nerve block

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Healthy adult patients 18–60 years old Having a mandibular premolar tooth with symptomatic irreversible pulpitis Normal periapical radiographic appearance

Exclusion criteria:
History of sensitivity to 4%articaine or epinephrine Systemic diseases Pregnancy or breastfeeding Any type of medication that could potentially interact with the anesthetic solution Spontaneous pain Periodontal disease or unable to get restoration Having pain killer late 12 hours

Age
From **18 years** old to **60 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **64**
Actual sample size reached: **64**

Randomization (investigator's opinion)
Randomized

Randomization description
Simple randomizzation individually 3 categories (1.8 articaine, 3.6 articaine) were written on 64pieces of paper and kept in sealed envelopes.

Blinding (investigator's opinion)
Double blinded

Blinding description
The first practitioner who perform the local anesthetic injection will open the envelope, and based on the category each patient will receive either 2 cartridges of the anesthetic solution or a cartridge of the anesthetic solution followed by a mock injection. Another practitioner will perform the rest of the treatment including access cavity preparation and root canal instrumentation. Hence, the second practitioner and the patients won't be aware of the volume of anesthetic solution used.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Rafsanjan University of Medical Sciences

Street address
Imam Ali Blv.

City
rafsanjan

Province
Kerman

Postal code
7717933777

Approval date
2022-12-26, 1401/10/05

Ethics committee reference number
IR.RUMS.REC.1401.185

Health conditions studied

1

Description of health condition studied
irreversible pulpitis of the mandibular premolar

ICD-10 code
pulpitis

ICD-10 code description
k04.0

Primary outcomes

1

Description
Pain score during treatment on Visual Analogue Scale (VAS)

Timepoint
before administration of the anesthetic solution and during the endodontic treatment

Method of measurement
Visual Analogue Scale (VAS)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: The mental nerve block involved a deposition of 1.8 mL 4% articaine with1:100,000 epinephrine (Artinibsa, Inibsa, Barcelona, Spain) each patient received a cartridge of the anesthetic solution

followed by a mock injection. The treatment including access cavity preparation and root canal instrumentation were performed 2-3 minutes after the injection. The patients were asked to rate their pain using a Heft-Parkervisual analog pain scale (VAS) before administration of the anesthetic solution and during the endodontic treatment.

Category

Treatment - Drugs

2

Description

Intervention group: The mental nerve block involved adeposition of 3.6mL 4% articaine with1:100,000 epinephrine (Artinibsa, Inibsa, Barcelona, Spain) each patient received 2 cartridges of the anesthetic solution. the treatment including access cavity preparation and root canal instrumentation were performed 2-3 minutes after the injection. The patients were asked to rate their pain using a Heft-Parkervisual analog pain scale (VAS) before administration of the anesthetic solution and during the endodontic treatment.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Private Clinic
Full name of responsible person
Ramin Abazarpoor
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Rafsanjan University of Medical Sciences
Full name of responsible person
Ali Shamsizadeh
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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

Rafsanjan 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
Rafsanjan University of Medical Sciences
Full name of responsible person
Ramin Abazarpoor
Position
Assistant professor
Latest degree
Specialist
Other areas of specialty/work
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Person responsible for scientific inquiries

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
There is no more information

Study Protocol
No - There is not a plan to make this available

Statistical Analysis Plan
No - There is not a plan to make this available

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
No - There is not a plan to make this available

Analytic Code
No - There is not a plan to make this available

Data Dictionary
No - There is not a plan to make this available