Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Comparative evaluation of anesthetic efficacy of 1.8 mL articaine, 1.8 mL and 3.6 mL of lidocaine for mental nerve block in mandibular premolar with irreversible pulpitis

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 1.8 lidocaine 2% mental nerve block in mandibular premolar with irreversible pulpitis by age and gender Determine success rate of 3.6 lidocaine 2% mental nerve block in mandibular premolar with irreversible pulpitis by age and gender Comparison of success rate in all 3 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, 3.6 ml of 2% lidocaine solution (two anesthetic cartridges three minutes apart), in the second group, 1.8 ml of 4% articaine solution (one anesthetic cartridge and three minutes later followed by a moking injection), the third group 1.8 ml of 2% lidocaine solution (an 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: **IRCT20210515051306N1**
Registration date: **2021-07-07, 1400/04/16**
Registration timing: **registered_while_recruiting**

Last update: **2021-07-07, 1400/04/16**
Update count: **0**

Registration date
2021-07-07, 1400/04/16

Registrant information

Name
Ramin Abazarpoor

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
2021-06-22, 1400/04/01

Expected recruitment end date
2021-08-01, 1400/05/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative evaluation of anesthetic efficacy of 1.8 mL articaine, 1.8 mL and 3.6 mL of lidocaine for mental nerve block in mandibular premolar with irreversible pulpitis

Public title

anesthetic efficacy of 1.8 mL articaine, 1.8 mL and 3.6 mL of lidocaine for mental nerve block in irreversible pulpitis of the mandibular premolar

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
- Care provider

Sample size

Target sample size: **165**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomizzation individually 3 categories (1.8 lidocaine, 1.8 articaine and 3.6 lidocaine) were written on 165 pieces 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

2021-06-22, 1400/04/01

Ethics committee reference number

IR.RUMS.REC.1400.053

Health conditions studied

1

Description of health condition studied

irreversible pulpitis of the mandibular premolar

ICD-10 code

K04.0

ICD-10 code description

Pulpitis

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
1st Intervention group: The mental nerve block involved adeposition of 1.8 mL 2% lidocaine with1:80,000 epinephrine (Xilonibsa, 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

2

Description
2nd 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

3

Description
3rd Intervention group: The mental nerve block involved adeposition of 1.8 mL 2% lidocaine with1:80,000 epinephrine (Xilonibsa, 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

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
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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
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
Dentistry

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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