

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

11 Sep 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 Abazarpour

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 34 3424 2322

##### Email address

abazarpour@rums.ac.ir

##### 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 randomization 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 a deposition of 1.8 mL 2% lidocaine with 1:80,000 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 with 1:100,000 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 a deposition of 1.8 mL 2% lidocaine with 1:80,000 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 Abazarpour

#### Street address

Dental Clinic, Sarallah St., Imam Khomeini Blvd.

#### City

Rafsanjan

#### Province

Kerman

#### Postal code

7719757047

#### Phone

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#### Email

ram\_aba@yahoo.com

## Sponsors / Funding sources

## 1

### Sponsor

#### Name of organization / entity

Rafsanjan University of Medical Sciences

#### Full name of responsible person

Ali Shamsizadeh

#### Street address

Dentistry school, Khalij-e fars Blvd.

#### City

Rafsanjan

#### Province

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#### Postal code

7717931136

#### Phone

+98 34 3428 0031

#### Email

ram\_aba@yahoo.com

#### 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 Abazarpour

#### Position

Assistant professor

#### Latest degree

Specialist

#### Other areas of specialty/work

Dentistry

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**Person responsible for scientific inquiries****Contact****Name of organization / entity**

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**Full name of responsible person**

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**Position**

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**Latest degree**

Specialist

**Other areas of specialty/work**

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Rafsanjan University of Medical Sciences

**Full name of responsible person**

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**Position**

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**Latest degree**

Specialist

**Other areas of specialty/work**

Dentistry

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**Fax****Email**

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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