

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 2026

### Investigating the success rate of infiltrating anesthetic injection of 1.8 ml of Articaine, injection of 1.8 ml of Articaine as mental block and injection of 1.8 ml of Lidocaine as mental block in mandibular incisor teeth with irreversible pulpitis: A randomized clinical trial

#### Protocol summary

##### Study aim

Determine success rate of infiltrating anesthetic injection of 1.8 ml of Articaine, injection of 1.8 ml of Articaine as mental block and injection of 1.8 ml of Lidocaine as mental block in mandibular incisor teeth with irreversible pulpitis

##### Design

Randomized, 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-blind). patients are instructed to report any pain at any stage of treatment in Visual Analogue Scale (VAS) form.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Healthy adult patients 18 to 60 years old having mandibular canine with symptomatic irreversible pulpitis and normal periapical radiograph appearance Exclusion criteria: Increasing the width of the periodontal ligament or radiolucency in radiography; canine teeth sensitive to pressure; sensitivity to articaine 4% or lidocaine 2% or epinephrine; American Society of Anesthesiologists (ASA) III, IV patients; pregnancy or breastfeeding; Addicted patients

##### Intervention groups

In the first group, infiltrating of 1.8 ml of 4% Articaine solution, the second group of 1.8 ml of 4% Articaine solution as mental block and the third group of 1.8 ml of 2% Lidocaine solution as mental block . 10 minutes after the anesthetic injection, the patient is asked about the numbness of the lower lip, and if the answer is negative, he is excluded from the study, and 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,IP,PDL

##### IRCT registration information

IRCT registration number: **IRCT20210515051306N3**

Registration date: **2023-07-16, 1402/04/25**

Registration timing: **prospective**

Last update: **2023-07-16, 1402/04/25**

Update count: **0**

##### Registration date

2023-07-16, 1402/04/25

##### 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

2023-08-06, 1402/05/15

##### Expected recruitment end date

2023-09-06, 1402/06/15

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Investigating the success rate of infiltrating anesthetic injection of 1.8 ml of Articaine, injection of 1.8 ml of Articaine as mental block and injection of 1.8 ml of Lidocaine as mental block in mandibular incisor teeth with irreversible pulpitis: A randomized clinical trial

**Public title**

The success rate of infiltrating anesthetic injection of 1.8 ml of Articaine, injection of 1.8 ml of Articaine as mental block and injection of 1.8 ml of Lidocaine as mental block in mandibular incisor teeth with irreversible pulpitis: A randomized clinical trial

**Purpose**

Treatment

**Inclusion/Exclusion criteria**

**Inclusion criteria:**

Healthy adult patients 18\_60 years old Having a mandibular incisor tooth with symptomatic irreversible pulpitis Normal periapical radiographic appearance

**Exclusion criteria:**

Patients under age of 18 and over the age of 60 years American Society of Anesthesiologists (ASA) III,IV patients 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 History of sensitivity to 4% articaine, 2% lidocaine or epinephrine Widening PDL Radiolucency in radiography Incisor teeth sensitive to percussion Addicted

**Age**

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

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **165**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Simple randomization individually 3 categories (Infiltrating anesthetic injection of 1.8 ml of Articaine, injection of 1.8 ml of Articaine as mental block and injection of 1.8 ml of Lidocaine as mental block ) were written on 165 pieces of paper and kept in sealed envelopes.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

The papers are placed in the envelope and before each

injection, another dentist colleague takes them out by chance, and written injection is done by him so that the operator and patient are not aware of the type of anesthesia technique.

**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 Blvd , Central Organization

**City**

Rafsanjan

**Province**

Kerman

**Postal code**

7717933777

**Approval date**

2023-06-24, 1402/04/03

**Ethics committee reference number**

IR.RUMS.REC.1402.041

**Health conditions studied**

**1**

**Description of health condition studied**

Irreversible pulpitis of the mandibular incisor

**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 root canal treatment

**Method of measurement**

Visual Analogue Scale (VAS)

**Secondary outcomes**

empty

## Intervention groups

### 1

#### Description

Intervention group: First intervention group: The first group of infiltrating anesthetic injection of 1.8 ml of 4% articaine solution with 1.100000 epinephrine, using the methods mentioned in Malamed. 10 minutes after the anesthetic injection, the patient is asked about the numbness of the lower lip, and if the answer is negative, he is excluded from the study, and if the answer is positive, the tooth is isolated by a rubber band, and the caries is removed. The access hole is prepared and root canal preparation is done. Patients are taught to report any pain during each stage of the preparation of the access hole and the entry of the instrument into the canal and cleaning to be recorded in the VAS form.

#### Category

Treatment - Drugs

### 2

#### Description

Intervention group: Second intervention group: The second group of mental nerve block is injected with 1.8 ml of 4% articaine solution with 1.100000 epinephrine, using the methods mentioned in Malamed. 10 minutes after the anesthetic injection, the patient is asked about the numbness of the lower lip, and if the answer is negative, he is excluded from the study, and if the answer is positive, the tooth is isolated by a rubber band, and the caries is removed. The access hole is prepared and root canal preparation is done. Patients are taught to report any pain during each stage of the preparation of the access hole and the entry of the instrument into the canal and cleaning to be recorded in the VAS form.

#### Category

Treatment - Drugs

### 3

#### Description

Intervention group: The third intervention group: The third group of mental nerve block is injected with 1.8 ml of 2% lidocaine solution with 1.100000 epinephrine, using the methods mentioned in Malamed. 10 minutes after the anesthetic injection, the patient is asked about the numbness of the lower lip, and if the answer is negative, he is excluded from the study, and if the answer is positive, the tooth is isolated by a rubber band, and the caries is removed. The access hole is prepared and root canal preparation is done. Patients are taught to report any pain during each stage of the preparation of the access hole and the entry of the instrument into the canal and cleaning to be recorded in the VAS form.

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Private Clinic

##### Full name of responsible person

Ramin Abazarpour

##### Street address

Imam Khomeini Blvd., 37 Alley

##### City

Rafsanjan

##### Province

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##### Postal code

7713816120

##### Phone

+98 34 3425 2366

##### Email

ram\_aba@yahoo.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Rafsanjan University of Medical Sciences

##### Full name of responsible person

Reza Vazirinejad

##### Street address

Khalij-e fars Blvd., Medical School

##### City

Rafsanjan

##### Province

Kerman

##### Postal code

37718175911

##### Phone

+98 34 3131 5512

##### Email

rvazirinejad@yahoo.co.uk

#### Grant name

#### Grant code / Reference number

#### Is the source of funding the same sponsor organization/entity?

No

#### 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**

Ramin Abazarpoor

**Full name of responsible person**

Rafsanjan University of Medical Sciences

**Position**

Assistant professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Dentistry

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## Person responsible for scientific inquiries

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## Person responsible for updating data

### Contact

**Name of organization / entity**

Rafsanjan University of Medical Sciences

**Full name of responsible person**

Ramin Abazarpoor

**Position**

Assistant professor

**Latest degree**

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**Other areas of specialty/work**

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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