

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

07 Jul 2026

### Comparative evaluation of anesthetic efficacy of 1.8 milliliter Articaine and 3.6 milliliter of Articaine for infiltration anesthesia in mandibular canins with irreversible pulpitis: A randomized clinical

#### Protocol summary

##### Study aim

Determining the success rate of infiltration anesthesia injection of 1.8 milliliter Articaine and 3.6 milliliter Articaine in mandibular canins teeth with irreversible pulpitis

##### Design

A clinical trial Consists of two intervention groups, with parallel groups, double-blind, randomized, on 84 patients, sealed envelopes will be used for randomization.

##### Settings and conduct

The study will be performed by 2 dentists in a private clinic in Rafsanjan. Before each injection, another dentist will randomly take out a piece of paper from the sealed envelope and according to the number, he will inject one of the two anesthetic volumes, so that in the first group, 1.8 milliliter of 4% Articaine solution (one anesthetic cartridge and three minutes later, the needle will be inserted into the anesthetic area without injection) and the second group, 3.6 milliliter of 4% Articaine solution (two anesthetic cartridges three minutes apart) so that the operator and the patient are not aware of the anesthesia volume. Patients are instructed to report any pain at any stage of Root canal treatment in Heft-Parker Visual Analog Scale form.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria:Healthy adult patients 18-60 years old having mandibular canins tooth with symptomatic irreversible pulpitis. exclusion criteria:Spontaneous pain and patients who need emergency treatment.

##### Intervention groups

In the 1st group, 1.8 milliliter of Articaine solution and in the second group, 3.6 milliliter of Articaine solution. 6 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

##### IRCT registration information

IRCT registration number: **IRCT20091213002847N5**

Registration date: **2023-08-04, 1402/05/13**

Registration timing: **retrospective**

Last update: **2023-08-04, 1402/05/13**

Update count: **0**

##### Registration date

2023-08-04, 1402/05/13

##### Registrant information

##### Name

Mohammad Mahdi Yaghooti Khorasani

##### Name of organization / entity

Dental School, Golestan University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 17 3262 7327

##### Email address

dr.yaghooti@goums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2023-04-05, 1402/01/16

##### Expected recruitment end date

2023-06-10, 1402/03/20  
**Actual recruitment start date**  
2023-04-05, 1402/01/16  
**Actual recruitment end date**  
2023-06-15, 1402/03/25  
**Trial completion date**  
2023-06-15, 1402/03/25

#### Scientific title

Comparative evaluation of anesthetic efficacy of 1.8 milliliter Articaine and 3.6 milliliter of Articaine for infiltration anesthesia in mandibular canines with irreversible pulpitis: A randomized clinical

#### Public title

infiltration anesthetic efficacy of Articaine for mandibular canines

#### Purpose

Treatment

#### Inclusion/Exclusion criteria

##### Inclusion criteria:

Healthy patients who have no systemic disease limiting dental treatment in their history Age range from 18 to 60 years has a mandibular canine with irreversible pulpitis and a normal periapical radiograph that not require emergency treatment. The patient has informed consent to participate in the study

##### 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 analgesic 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: **90**

Actual sample size reached: **84**

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

Simple randomization individually with using a sealed envelope The even and odd numbers from 1 to 84 (even numbers for injection of 2 cartridge articaine 4% and odd numbers for injection of 1 cartridge articaine 4%) are write on separate papers and placed in the one sealed envelope, and another dentist colleague randomly takes out a number from the envelope for each patient and performs an injection based on that.

#### Blinding (investigator's opinion)

Double blinded

#### Blinding description

Before each injection, another dentist will randomly take

out a piece of paper and according to the number, he will inject one of the two anesthetic volumes, so that in the first group, 1.8 milliliter of 4% Articaine solution (one anesthetic cartridge and three minutes later, the needle will be inserted into the anesthetic area without injection) and the second group, 3.6 milliliter of 4% Articaine solution (two anesthetic cartridges three minutes apart) so that the operator and the patient are not aware of the anesthesia volume.

#### Placebo

Not used

#### Assignment

Parallel

#### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Rafsanjan University of Medical Sciences

##### Street address

Imam Ali

##### City

Rafsanjan

##### Province

Kerman

##### Postal code

7717933777

#### Approval date

2023-03-14, 1401/12/23

#### Ethics committee reference number

IR.RUMS.REC.1401.250

## Health conditions studied

### 1

#### Description of health condition studied

Pain during root canal treatment

#### ICD-10 code

#### ICD-10 code description

## Primary outcomes

### 1

#### Description

Pain during root canal treatment

#### Timepoint

During access hole preparation, dentin entry, pulp chamber entry or file placement

#### Method of measurement

Visual Analogue Scale (VAS)

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

1st Intervention group: In the first group, infiltration injection of 1.8 milliliter of Articaine solution (Inibsa, Barcelona, Spain) is used. The treatment including access cavity preparation and root canal instrumentation were performed 6 minutes after the injection. Patients are taught to report any pain during each stage of preparation of the access hole and the entry of the instrument into the canal and cleaning and shaping to be recorded in the Heft-Parker visual analog pain scale (VAS) form.

#### Category

Treatment - Drugs

### 2

#### Description

Intervention group: : 2st Intervention group: In the second group, infiltration injection of 3.6 milliliter of Articaine solution (Inibsa, Barcelona, Spain) is used. The treatment including access cavity preparation and root canal instrumentation were performed 6 minutes after the injection. Patients are taught to report any pain during each stage of preparation of the access hole and the entry of the instrument into the canal and cleaning and shaping to be recorded in the Heft-Parker visual analog pain scale (VAS) form.

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Personal office

##### Full name of responsible person

Ramin Abazarpour

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##### Phone

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## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Rafsanjan University of Medical Sciences

##### Full name of responsible person

Dr Reza Vazirinezhad

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rvazirinejad@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

Mohammad Mahdi Yaghooti Khorasani

##### Position

Associated Professor of Endodontics

##### Latest degree

Specialist

##### Other areas of specialty/work

Dentistry

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## Person responsible for scientific inquiries

### Contact

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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