Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Comparative evaluation of anesthetic efficacy of 1.8 milliliter Articaine and 3.6 milliliter of Articaine for infilteration 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

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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 infilteration anesthesia in mandibular canins with irreversible pulpitis: A randomized clinical

Public title

infiltration anesthetic efficacy of Articaine for mandibular canins

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 randomizzation 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
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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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
Mohammad Mahdi Yaghooti Khorasani
Position
Associated Professor of Endodontics
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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