Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Comparation of infiltration anesthetic efficacy of 1.8 ml and 3.6 ml of articaine for mandibular incisor in irreversible pulpitis: A randomized clinical trial

Protocol summary

Study aim

Determining the success rate of infiltration anesthesia injection of one articaine cartridge in mandibular incisor teeth with irreversible pulpitis according to gender and age and determining the success rate of infiltration anesthesia injection of two articaine cartridges in mandibular incisor teeth with irreversible pulpitis According to gender and age and comparing the success rate of anesthetic solution in 2 studied groups.

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 Heft-Parker Visual Analog Scale form.

Participants/Inclusion and exclusion criteria

Healthy adult patients 18–60 years old having mandibular incisor tooth with symptomatic irreversible pulpitis and a normal periapical radiographic appearance

Intervention groups

In the 1st group, 3.6 ml of articaine solution (two anesthetic cartridges three minutes apart), in the second group, 1.8 ml of articaine solution (one 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

IRCT registration information

IRCT registration number: **IRCT20091213002847N4**
Registration date: **2023-07-22, 1402/04/31**
Registration timing: **retrospective**

Last update: **2023-07-22, 1402/04/31**
Update count: **0**

Registration date

2023-07-22, 1402/04/31

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
2023-06-16, 1402/03/26

Scientific title
Comparation of infiltration anesthetic efficacy of 1.8 ml and 3.6 ml of articaine for mandibular incisor in irreversible pulpitis: A randomized clinical trial

Public title
infiltration anesthetic efficacy of 1.8 ml and 3.6 ml of articaine for mandibular incisor in irreversible pulpitis

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Healthy patients With Mandibular Incisor teeth with irreversible pulpitis and normal Periapical Radiography Without Spontaneous pain that required Emergency treatment

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: **88**

Randomization (investigator's opinion)
Randomized

Randomization description
Simple randomizzation The even and odd numbers from 1 to 88 (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
The numbers 1 to 88 are written on cards and placed inside an envelope, where even and odd numbers each represent one of the two volumes of anesthetic drug, which is chosen by another colleague by chance, and the corresponding injection is made by him until the patient and the operator. Do not know the amount of anesthetic.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Rafsanjan university of medical science

Street address
Imam Ali Blvd

City
Rafsanjan

Province
Kerman

Postal code
7717933777

Approval date
2023-03-14, 1401/12/23

Ethics committee reference number
IR.RUMS.REC.1401.251

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 the preparation of the access hole, entering the dentin, entering the pulp chamber or placing the file in the canal

Method of measurement
VAS

Secondary outcomes

empty

Intervention groups

1

Description
1st Intervention group: The infiltration involved adeposition of 1.8 mL articaine (Xilonibsa, Inibsa, Barcelona, Spain) each patient received 1 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

2st Intervention group: The infiltration involved adeposition of 3.6 mL articaine (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

Recruitment centers

1

Recruitment center

Name of recruitment center
Personal office

Full name of responsible person
Ramin Abazarpoor

Street address
Imam Khomeini

City
Rafsanjan

Province
Kerman

Postal code
7717933777

Phone
+98 34 3424 2322

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 Vazirinezhad (Vice President of Research and Technology of RUMS)

Street address
Imam Ali

City
Rafsanjan

Province
Kerman

Postal code
7717933777

Phone
+98 34 3428 0040

Email
vcrt@rums.ac.ir

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 Yaaghooti Khorasani

Position
Associate Professor

Latest degree
Specialist

Other areas of specialty/work
Endodontics

Street address
Imam Ali

City
Rafsanjan

Province
Kerman

Postal code
7717933777

Phone
+98 34 3428 0040

Email
m.yaghooti@yahoo.com

Person responsible for scientific 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

Street address

Dental School, Shahid Mofateh Blvd.

City
Rafsanjan

Province
Kerman

Postal code
7717933777

Phone
+98 34 3428 0031

Fax
+98 34 3428 0008

Email
m_yaghooti@rums.ac.ir

Person responsible for updating data

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

Street address
Dental School, Shahid Mofateh Blvd.

City
Rafsanjan

Province
Kerman

Postal code
7717933777

Phone
+98 34 3428 0031

Fax
+98 34 3428 0008

Email
m_yaghooti@rums.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Yes - There is a plan to make this available

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
All data is potentially shareable after de-identifying individuals

When the data will become available and for how long
The access period starts 6 months after the results are published

To whom data/document is available
Researchers in the fields of medical sciences

Under which criteria data/document could be used
There is no limit

From where data/document is obtainable
Email to Mohammad Mahdi Yaaghooti Khorasani m.yaghooti@yahoo.com

What processes are involved for a request to access data/document
By emailing the scientific officer and requesting to receive information, the information will be sent to the sender's email within 15 days

Comments