Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

A comparison between anesthetic efficacy of articaine and lidocaine secondary endodontic treatment in mandibular molar teeth : A randomized clinical trial

Protocol summary

Study aim

Determination and Comparison of the Success of Articaine and Lidocaine Anesthesia During and After Endodontic Retreatment in Mandibular Molars: A Randomized Clinical Trial

Design

A controlled clinical trial, with parallel groups, double-blind, randomized, using the Sealed Envelope website for randomization.

Settings and conduct

This double-blind clinical trial will be conducted on 60 patients who have been referred to the Kerman Dental School and have asymptomatic, endodontically treated mandibular molars diagnosed as requiring retreatment. The patients will be randomly allocated into two groups.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Asymptomatic patients with mandibular molars requiring retreatment that are restorable. Exclusion Criteria: Symptomatic patients with mandibular molars not requiring retreatment or that are non-restorable.

Intervention groups

Intervention group: Use of supplementary infiltration injection of Articaine after mandibular block injection with Lidocaine in root canal retreatment of manibular molars Control group: Use of mandibular block injection with Lidocaine in root canal retreatment of manibular molars

Main outcome variables

Investigating the effect of the type of anesthetic agent on pain level during retreatment of asymptomatic mandibular first and second molars؛ Investigating the effect of the anesthetic technique on pain level during retreatment of asymptomatic mandibular molars؛ Investigating the effect of the anesthetic technique on pain level after retreatment of asymptomatic mandibular molars؛ Assessing the quality of life before, during, and after retreatment of asymptomatic mandibular molars using either lidocaine block or articaine infiltration anesthesia.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20260122068639N1**
Registration date: **2026-02-16, 1404/11/27**
Registration timing: **registered_while_recruiting**

Last update: **2026-02-16, 1404/11/27**
Update count: **0**

Registration date

2026-02-16, 1404/11/27

Registrant information

Name
mohammad moradinia
Name of organization / entity
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Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2026-02-14, 1404/11/25

Expected recruitment end date

2026-04-25, 1405/02/05

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
A comparison between anesthetic efficacy of articaine and lidocaine secondary endodontic treatment in mandibular molar teeth : A randomized clinical trial

Public title
anesthesia in root canal retreatment
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
– First or second mandibular molars with a history of root canal treatment having a Periapical Index (PAI) score of 1, 2, or 3. Teeth previously treated with root canal therapy but unsuccessful and having developed apical periodontitis (AP). Individuals with a spontaneous pain score of less than 54 mm on the HP-VAS scale Teeth with radiographically poor-quality root canal fillings. Teeth with failed or insufficient coronal restoration requiring root canal retreatment. Patients aged 18 to 65 years Patients with ASA I and ASA II Patients without acute pain or extracoral swelling Patients with acute apical abscess Patients who voluntarily participate in the study and are available for follow-up Absence of severe periodontal problem in the tooth in question Teeth with prefabricated posts
Exclusion criteria:
Individuals with a spontaneous pain score greater than 54 on the HP-VAS scale Patients whose retreatment requires two sessions.– Teeth with internal or external root resorption Teeth with vertical root fracture or dental crack Teeth with open or immature apex Patients with systemic diseases (such as bone metabolism disorders) Patients taking medications affecting bone metabolism Patients with acute pain who have taken analgesics in the past 24 hours Patients who did not attend follow-up sessions third molars Presence of severe periodontal disease rendering the tooth unsuitable for endodontic treatment Periodontal probing depth greater than 3 mm. Root canal treatment extending beyond the canal length and over instrumentation Teeth with cast posts or broken files inside the canal Patients with contraindications to NSAIDs Patients who experience treatment errors during retreatment Patients who are accidentally over-instrumented during the procedure Patients in whom post-operative radiography shows any extrusion of the root canal filling material Teeth with extensive caries making restoration impossible
Age
From **18 years** old to **65 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
Patients will be randomly divided into two groups, Group A and Group B: Lidocaine VS Articaine (Men) and Lidocaine VS Articaine (Women), using the website www.SealedEnvelope.com. Each patient, after entering the study, will determine their group by selecting the word "Randomization".
Blinding (investigator's opinion)
Double blinded
Blinding description
The anesthetic injection is performed by two endodontic specialty residents (other than the main operator) who have rehearsed and calibrated the block and infiltration injection techniques in a separate session.
Placebo
Not used
Assignment
Crossover
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Kerman University of Medical Sciences Ethics Committee
Street address
Kerman, Jomhori Esalmi Blvd, Shafa Street
City
Kerman
Province
Kerman
Postal code
7618759689
Approval date
2025-11-02, 1404/08/11
Ethics committee reference number
IR.KMU.REC.1404.426

Health conditions studied

1

Description of health condition studied
Root canal retreatment of mandibular molars
ICD-10 code
K04.9
ICD-10 code description
Other and unspecified diseases of pulp and periapical tissues

Primary outcomes

1

Description
Pain score in the Heft-Parker Visual Analog Scale (HP-VAS) questionnaire
Timepoint
Before the start of treatmentDuring the injectionDuring removal of the coronal restorationDuring removal of gutta-percha from the canalsDuring canal preparation and irrigationDuring obturationImmediately after completion of the procedure,6 hours after the procedure,12 hours after the procedure, 24 hours after the procedure, 2 days after the procedure, 3 days after the procedure،7 days after the procedure
Method of measurement
Heft-Parker Visual Analog Scale (HP-VAS) questionnaire

Secondary outcomes

1

Description
quality of life score
Timepoint
Before the start of treatment, 7 days after treatment
Method of measurement
Oral Health Impact Profile-14 (OHIP-14) questionnaire

Intervention groups

1

Description
Intervention group: Use of supplementary infiltration injection of Articaine after mandibular block injection with Lidocaine in root canal retreatment of manibular molars
Category
Treatment - Other

2

Description
Control group: Use of mandibular block injection with Lidocaine in root canal retreatment of manibular molars
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
School of dentistry, Kerman University of Medical sciences
Full name of responsible person
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Sponsors / Funding sources

1

Sponsor
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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
Kerman 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

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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
A portion of the data, such as information related to the main message or similar items, can be shared
When the data will become available and for how long
The access period begins one year after the results are published
To whom data/document is available
It will only be available to researchers employed at academic and scientific institutions
Under which criteria data/document could be used
Use of the information is permitted solely for scientific purposes
From where data/document is obtainable
Email address: m.moradinia.g@gmail.com
What processes are involved for a request to access data/document
By sending an email to the mentioned address, the documentation will reach them after one week
Comments