Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Evaluation of postoperative pain intensity after retreatment of mandibular molar teeth obturated with gutta-percha, Mineral Trioxide Aggregate (MTA), and Cold Ceramic

Protocol summary

Study aim
Assessment of pain intensity following endodontic retreatment of asymptomatic mandibular molars with Gutta-Percha, Mineral Trioxide Aggregate, and Cold Ceramic

Design
An interventional, single-blind, randomized, parallel, phase 2/3 clinical trial on 60 patients

Settings and conduct
All procedures will be performed by an endodontist at the Endodontic Clinic, Kurdistan University of Medical Sciences. After local anesthesia and isolation, canal access will be established and prepared with M3-Pro Gold rotary files, with working length determined using an apex locator (Root ZX) and radiographs. Apical patency will be ensured with a #10 K-file. Patients will be assigned to three groups: A: Obturation with Gutta-percha using the cold lateral compaction technique B: Obturation with Mineral Trioxide Aggregate (MTA) (Angelus, Brazil), Apical as an MTA plug and coronal by the backfill method C: Obturation with Cold Ceramic (Samin, Iran), Apical as a plug and coronal using the backfill method Pain intensity will be recorded at 8, 24, 48, and 72 hours using the Visual Analog Scale (VAS)

Participants/Inclusion and exclusion criteria
Inclusion Criteria: Patients with at least one mandibular molar requiring retreatment, with asymptomatic teeth and periapical radiographic lesions, and systemically healthy, will be included in the study Exclusion Criteria: Patients with uncontrolled systemic diseases, pregnant women, and those with acute periapical infections causing swelling and abscess will be excluded from the study

Intervention groups
Group A : Gutta-percha using cold lateral compaction Group B: Mineral Trioxide Aggregate, apical plug and coronal backfill Group C: Cold Ceramic, apical plug and coronal backfill

Main outcome variables
Pain intensity after retreatment of mandibular molars obturated with three root canal filling materials: Gutta-percha, Mineral Trioxide Aggregate, and Cold Ceramic

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20251003067492N1**
Registration date: **2025-10-12, 1404/07/20**
Registration timing: **prospective**

Last update: **2025-10-12, 1404/07/20**
Update count: **0**

Registration date
2025-10-12, 1404/07/20

Registrant information

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Name of organization / entity
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2025-11-16, 1404/08/25

Expected recruitment end date

2025-12-16, 1404/09/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of postoperative pain intensity after retreatment of mandibular molar teeth obturated with gutta-percha, Mineral Trioxide Aggregate (MTA), and Cold Ceramic

Public title

Comparison of pain intensity following endodontic retreatment of mandibular molars with Gutta-Percha, Mineral Trioxide Aggregate (MTA), and Cold Ceramic: A randomized clinical trial

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with asymptomatic mandibular molars requiring endodontic retreatment. Presence of periapical radiolucency on the target tooth. Patients aged over 18 years and under 60 years. Patients able and willing to provide informed consent.

Exclusion criteria:

Presence of uncontrolled systemic diseases. Presence of non-odontogenic or chronic pain.

Age

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

Gender

Both

Phase

2-3

Groups that have been masked

- Participant

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

The study will be conducted in three treatment groups, as detailed below: 1. Group A : Root canal obturation with Gutta-Percha using Cold Lateral Compaction (CLC) technique. 2. Group B: Root canal obturation with MTA (Angelus, Brazil): the apical one-third is filled with an MTA plug, and the coronal two-thirds are filled using the Backfill technique. 3. Group C: Root canal obturation with Cold Ceramic (Samin, Iran), First, the apical plug is placed, followed by the coronal backfill. • Randomization in this study will be performed using the block randomization method to allocate participants into groups. The final sample size will include 60 participants. The blocks consist of three units and are arranged in a combination of A, B, and C. The final number of blocks is six, and their sequence is as follows: 1. ABC 2. ACB 3. BAC 4. BCA 5. CBA 6. CAB To select the blocks, a random number table is used. In this method, we start from the first number in the table and move from left to right. Whenever a number between 1 and 6 appears, the corresponding block is selected, and numbers outside this range are ignored.

Blinding (investigator's opinion)

Single blinded

Blinding description

Patients will not be aware of the type of canal filling material used.

Placebo

Not used

Assignment

Parallel

Other design features

This is a randomized, single-blind, parallel, interventional clinical trial, phase 2/3, conducted on 60 patients.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Kurdistan University of Medical Sciences

Street address

Pasdaran Ave, Kurdistan University of Medical Sciences

City

Sanandaj

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Kurdistan

Postal code

6617713491

Approval date

2025-09-30, 1404/07/08

Ethics committee reference number

IR.MUK.REC.1404.193

Health conditions studied

1

Description of health condition studied

Postoperative pain after retreatment of mandibular molar teeth

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Pain intensity after retreatment of mandibular molars obturated with three root canal filling materials: Gutta-percha, Mineral Trioxide Aggregate, and Cold Ceramic.

Timepoint

8, 24, 48, and 72 hours after treatment.

Method of measurement

Visual Analog Scale (VAS) questionnaire.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Obturation with Gutta-Percha using Cold Lateral Compaction (CLC).

Category

N/A

2

Description

Intervention group: Obturation with Mineral Trioxide Aggregate (MTA) (Angelus, Brazil): the apical one-third is filled with an MTA plug, and the coronal two-thirds are filled using Backfill.

Category

N/A

3

Description

Intervention group: Obturation with Cold Ceramic (Samin, Iran): an apical plug is placed followed by coronal Backfill

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Kurdistan University of Medical Sciences Dental Clinic

Full name of responsible person

Erfan Ahmadyani

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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?

No

Title of funding source

Sanandaj 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

Sanandaj University of Medical Sciences

Full name of responsible person

Erfan Ahmadyani

Position

Associate professor

Latest degree

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Other areas of specialty/work

Dentistry

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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
All data can be shared after de-identification of individual participants.

When the data will become available and for how long
Access will begin after the publication of the results.

To whom data/document is available
Researchers affiliated with academic and scientific institutions

Under which criteria data/document could be used
Researchers will have access to the data under any circumstances.

From where data/document is obtainable
For further information, you can contact the corresponding author via the following email: [ahmadyanierfan1@gmail.com]

What processes are involved for a request to access data/document
After sending a request via email to the corresponding author, the requester will have unlimited access to the data.

Comments