

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Comparison of pain after endodontic treatment using AH Plus sealer and CC sealer

Protocol summary

Study aim

Comparison of pain after endodontic treatment using AH Plus sealer and CC sealer

Design

Randomized controlled clinical trial using a simple random allocation method on 80 patients

Settings and conduct

80 patients with molars or premolars with irreversible pulpitis who refer to Shahid Sadoughi Dental School and meet the inclusion criteria will participate. All patients will be treated in a single session by the residents of the specialized department. First, the pain level before treatment is recorded based on the Verbal Rating Scale (VRS) as well as the periapical condition of the tooth in question, and patients are assigned to one of two groups, A or B, using a simple random assignment method. The patient is advised to take painkillers if they experience unbearable pain. Patients will be followed up by telephone at intervals of 6, 24, 48, and 72 hours after treatment to record the level of pain based on a verbal rating scale.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with mandibular molars or premolars with irreversible pulpitis. The tooth must be restorable. The root apex must be closed. Exclusion criteria: Patients' refusal to provide informed consent. Having another painful tooth in the same side of the mouth. The patient not being in a normal state of intelligence.

Intervention groups

Intervention group: After cleaning and shaping the root canal using rotary files and normal saline irrigation, gutta-percha and CC sealer (Samin, Iran) are used to obturation the root canal space in the same session. Control group: After cleaning and shaping the root canal using rotary files and normal saline irrigation, gutta-percha and AH Plus (Dentsply Sirona, USA) sealer are used to obturation the root canal space in the same session.

Main outcome variables

Pain after root canal treatment

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190315043057N2**

Registration date: **2026-01-31, 1404/11/11**

Registration timing: **prospective**

Last update: **2026-01-31, 1404/11/11**

Update count: **0**

Registration date

2026-01-31, 1404/11/11

Registrant information

Name

Jalil Modaresi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 35 3625 5881

Email address

j.modaresi@ssu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2026-02-09, 1404/11/20

Expected recruitment end date

2026-03-06, 1404/12/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of pain after endodontic treatment using AH Plus sealer and CC sealer

Public title

Comparison of post-treatment pain using two sealers: AH Plus and CC

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients with mandibular molars or premolars with irreversible pulpitis The tooth can be restored The root apex is closed.

Exclusion criteria:

patient dissatisfaction Having another painful tooth on the same side of the mouth The patient is not in a normal state in terms of intelligence.

AgeFrom **18 years** old**Gender**

Both

Phase

N/A

Groups that have been masked*No information***Sample size**Target sample size: **80****Randomization (investigator's opinion)**

Randomized

Randomization description

For randomization, the simple allocation method will be used, and in this study, the unit of randomization is the individual. To perform randomization, an allocation list will be generated in advance. For this purpose, using PASS software (version 2021) and selecting the "Simple Randomization" option, a random sequence for 80 participants will be generated. The software output will specify which of the two groups—'A' (recipient of AH Plus sealer) or 'B' (recipient of CC sealer)—each of the sequence numbers 1 to 80 belongs to. This list will be stored in an Excel file and will be accessible only to a research assistant who has no involvement in the enrollment and intervention processes. After determining the eligibility of each patient for entering the study and obtaining informed consent, the aforementioned assistant, based on the order of patient enrollment (first patient = number 1, second patient = number 2, etc.), will only announce the sequence number assigned to that patient. Then, based on the pre-generated list, the type of sealer (AH Plus or CC) will be determined, and the treatment will be performed by the endodontist. This method eliminates the possibility of predicting future group allocation.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of dental school of Shahid Sadoughi University of Medical Sciences

Street address

Imam Reza Blvd., Imam Reza Square

City

Yazd

Province

Yazd

Postal code

8914815667

Approval date

2025-08-02, 1404/05/11

Ethics committee reference number

IR.SSU.DENTISTRY.REC.1404.036

Health conditions studied**1****Description of health condition studied**

irreversible pulpitis

ICD-10 code

K04.0

ICD-10 code description

Pulpitis

Primary outcomes**1****Description**

post endodontic treatment pain

Timepoint

6 hours, 1,2 and 3 days after treatment

Method of measurement

pain verbal rating scale

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: For the teeth of patients in this group, after cleaning and shaping the root canal using a

rotary endodontic file and rinsing with normal saline, gutta-percha and CC sealer (Samin, Iran) are used when filling the root canal.

Category

Treatment - Drugs

2**Description**

Control group: For the teeth of patients in this group, after cleaning and shaping the root canal using a rotary endodontic file and rinsing with normal saline, gutta-percha and AH Plus sealer (Dentsply Sirona, USA) are used when filling the root canal.

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Shahid Sadoughi Dental School, Yazd

Full name of responsible person

Jalil Modaresi

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Yazd University of Medical Sciences

Full name of responsible person

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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

Yazd 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**

Yazd University of Medical Sciences

Full name of responsible person

Jalil Modaresi

Position

Professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Full name of responsible person

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Position

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Latest degree

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Other areas of specialty/work

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Person responsible for updating data

Contact

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available