Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparative analysis of postoperative pain in symptomatic irreversible pulpitis teeth following single cone obturation Using three Different Sealers: A Randomized Clinical Trial

Protocol summary

Study aim
Assessment and Comparison of Post-Endodontic Treatment Pain in Teeth with Irreversible Pulpitis Using Bioceramic Sealers (EndoSeal TCS and NeoSeal) vs. Resin-Based Sealer (AH Plus

Design
A Phase 2 randomized, double-blind clinical trial with parallel groups, including a control group, was conducted on 75 patients. The randomization process was carried out using the rand function in Microsoft Excel.

Settings and conduct
Double-blinding ensures unbiased pain assessment using the VAS scale. The study aims to identify optimal sealers for minimizing post-endodontic pain and guiding clinicians toward more effective treatment choices. Conducted at Tehran University's Dental School

Participants/Inclusion and exclusion criteria
This study evaluates post-treatment pain in patients aged 18–50 with symptomatic irreversible pulpitis in the first molars of the maxilla or mandible. Inclusion criteria involve adequate oral hygiene, prolonged positive responses to cold and electric pulp testing, and the absence of radiographic periapical lesions. Patients with complex anatomy, systemic diseases, or allergies to treatment materials are excluded.

Intervention groups
The two types of bioceramic sealers, Neosealer and Endoseal TCS, are being compared with the resin-based sealer AH Plus, as control group.

Main outcome variables
Pain intensity, the number of analgesic tablets consumed, the type of sealer prescribed, and the time of pain assessment.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20250510065680N1**
Registration date: **2025-07-01, 1404/04/10**
Registration timing: **prospective**

Last update: **2025-07-01, 1404/04/10**
Update count: **0**

Registration date
2025-07-01, 1404/04/10

Registrant information
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Somayeh Majidi
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2025-08-23, 1404/06/01

Expected recruitment end date
2025-11-22, 1404/09/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparative analysis of postoperative pain in

symptomatic irreversible pulpitis teeth following single cone obturation Using three Different Sealers: A Randomized Clinical Trial

Public title

Comparison of Different Types of Bioceramic Sealers on Post-Treatment Pain in Symptomatic Teeth

Purpose

Other

Inclusion/Exclusion criteria

Inclusion criteria:

Age Range of Patients: Between 18 and 50 years. Adequate Oral and Dental Hygiene. Prolonged Positive Response to Cold and Electric Pulp Tester. Patients Diagnosed with Symptomatic Irreversible Pulpitis and Symptomatic Apical Periodontitis in the First or Second Molar of the Maxilla or Mandible. Pulp Exposure During Caries Removal Accompanied by Severe and Thick Hemorrhage. Patients Without Radiographic Evidence of Periapical Lesions. Teeth with Restorative Potential. Patients Without Periodontal Problems.

Exclusion criteria:

Teeth with crowns that cannot be restored. presence of endo-perio lesion teeth with endodontic lesion Teeth with internal or external resorption calcified teeth Patients with systemic diseases and migraines classified as ASA II or higher Teeth with over or under obturation to 2mm from the apex Patients taking anti-anxiety medications. Cases with procedural duration exceeding two hours. Individuals allergic to materials used in root canal treatment, including local anesthetics.

Age

From **18 years** old to **50 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **75**

Randomization (investigator's opinion)

Randomized

Randomization description

Total Score Calculation The total score for each patient is determined by summing the points assigned to the type of medication, time of consumption, and dosage. This cumulative score is referred to as the "Analgesic Consumption Score." Stratified Randomization Patients are classified into different groups based on their analgesic consumption score before randomization: - Group 1: Low score (0–3) - Group 2: Moderate score (4–6) - Group 3: High score (7–10) Patients are further divided into subgroups based on two main factors: 1. Degree of analgesic consumption (as explained above) 2. Gender (male or female) Randomization Process For each possible combination of gender and analgesic consumption level, an envelope containing three sheets labeled with treatment groups A, B, and C is prepared. Considering both factors (gender and analgesic consumption level), the possible combinations are as follows: - Female, low analgesic consumption - Female, moderate analgesic consumption - Female, high analgesic consumption - Male, low analgesic consumption - Male, moderate analgesic consumption - Male, high analgesic consumption Thus, the total number of possible combinations is six. Preparation of Envelopes For each of the six combinations above, a separate envelope is prepared, each containing three sheets labeled A, B, and C. Consequently, a total of six envelopes must be prepared. Treatment Group Selection Process When a patient—e.g., a female with high analgesic consumption—arrives, they receive the envelope corresponding to their combination ("Female, high analgesic consumption") and select one of the sheets inside. If the patient selects Group A, subsequent patients with the same characteristics (female, high analgesic consumption) will only be able to choose between Groups B and C. This process continues until the number of patients in each treatment group reaches 25. Final Patient Distribution Ultimately, patients will be evenly distributed across the three treatment groups, ensuring that each group consists of 25 patients. This approach helps prevent biases related to gender or analgesic consumption levels.

Blinding (investigator's opinion)

Double blinded

Blinding description

The patient is unaware of the type of sealer used. Likewise, the operator remains blinded to the sealer type until the obturation phase, ensuring that their performance is not influenced by the specific sealer applied. Furthermore, in the post-treatment pain analysis, the operator does not participate in recording the patient's pain levels after the procedure. Instead, this task is conducted by a third-party evaluator to maintain objectivity and eliminate potential bias.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tehran University of Medical Sciences

Street address

No 605, Sixth Floor, Research and Technology Management Unit Central Headquarters of Tehran University of Medical Sciences Corner of Qods Street, Keshavarz Boulevard Tehran, Iran

City

Tehran

Province
Tehran
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۱۴۳۹۹۵۵۹34
Approval date
2025-05-04, 1404/02/14
Ethics committee reference number
IR.TUMS.DENTISTRY.REC.1404.021

Health conditions studied

1

Description of health condition studied
Comparison of post endodontic pain with various sealers
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Post endodontic therapy pain
Timepoint
First 8 hours post treatment, 24 h after, 48 h after
Method of measurement
Visual analog scale

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group 1 : Endoseal Tcs Sealer
Category
Treatment - Drugs

2

Description
Intervention group 2: Neosealer bioceramic sealer
Category
Treatment - Drugs

3

Description
Control group: AH plus sealer
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Tehran university school of dentistry clinics
Full name of responsible person
Somayeh Majidi
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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
Tehran 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
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Full name of responsible person
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Position
post graduate student of endodontics

Latest degree
Medical doctor

Other areas of specialty/work
Dentistry

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Latest degree
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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