

Official Study Title:

Comparative Analysis of Postoperative Pain in Symptomatic Irreversible Pulpitis Teeth Following Single Cone Obturation Using Three Different Sealers: A Randomized Clinical Trial

Document Date: 4 May 2025

Principal Investigator: Somayeh Majidi

Institution: Tehran University of Medical Sciences, Faculty of Dentistry, Tehran, Iran

Sponsor: Tehran University of Medical Sciences (100% funding)

Study Protocol Summary**1. Study Aim**

To assess and compare post-endodontic treatment pain in teeth with symptomatic irreversible pulpitis using two bioceramic sealers (EndoSeal TCS and NeoSeal) versus a resin-based sealer (AH Plus).

2. Study Design

- Phase 2, randomized, double-blind clinical trial with parallel groups.
- Total sample size: 75 patients.
- Randomization performed using Microsoft Excel's rand function.
- Double-blinded to ensure unbiased assessment of pain using the Visual Analog Scale (VAS).

3. Study Setting

- Conducted at Tehran University School of Dentistry clinics.
- Objective: Identify optimal sealer types to minimize post-endodontic pain and guide clinical decisions.

4. Participant Criteria**Inclusion Criteria:**

- Age 18–60 years
- Adequate oral hygiene
- Prolonged positive response to cold/electric pulp testing
- Diagnosis: Symptomatic irreversible pulpitis and symptomatic apical periodontitis in first or second molars
- Pulp exposure during caries removal with significant hemorrhage
- Teeth without radiographic periapical lesions, and with restorative potential
- No periodontal disease

Exclusion Criteria:

- Teeth unsuitable for restoration (e.g., crown cannot be restored)
- Endo-perio lesions, internal/external resorption, or calcified canals
- Systemic diseases (ASA II or higher)
- Use of anti-anxiety medications
- Procedural duration > 2 hours
- Allergies to treatment materials, including local anesthetics

5. Intervention Groups

1. **Endoseal TCS** – Bioceramic sealer
2. **NeoSeal** – Bioceramic sealer
3. **AH Plus** – Resin-based sealer (Control)

6. Randomization and Blinding

- Stratified randomization based on **gender** and **pre-treatment analgesic consumption score** (Low: 0–3, Moderate: 4–6, High: 7–10).
- Patients select an envelope corresponding to their combination, ensuring even distribution across three groups.
- Double-blinded: Neither operator nor patient knows sealer type during treatment; pain assessment performed by third-party evaluator.

7. Outcome Measures**Primary Outcome:**

- Post-endodontic pain intensity, measured using the Visual Analog Scale (VAS)
- Timepoints: 0–6 hours post-treatment, 12, 18, 24, 48 hours

Secondary Outcomes:

- Number of analgesic tablets consumed
- Time and type of analgesic use

8. Recruitment and Study Period

- Recruitment status: Active
- Location: Tehran University School of Dentistry Clinics

9. Ethics and Regulatory Information

- Ethics committee approval: Tehran University of Medical Sciences (IR.TUMS.DENTISTRY.REC.1404.021)
- Approval date: 04 May 2025
- Prospective registration: IRCT20250510065680N1, date 01 July 2025
- Compliance: 42 CFR Part 11, Common Rule (45 CFR 46)

10. Contacts

Principal Investigator: Somayeh Majidi

- Postgraduate Student of Endodontics, Faculty of Dentistry, Tehran University of Medical Sciences
- Email: dr.somaiejmaji@yahoo.com
- Phone: +98 21 4279 4000

Scientific Contact: Shole Ghabraei, Associate Professor, Endodontics

- Email: sholehghabraei@yahoo.com
- Phone: +98 21 4279 4000

Sponsor Contact: Dr. Ramin Kurdi, Tehran University of Medical Sciences

- Phone: +98 21 4279 4000