Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

The effect of AH26 and Resil resin sealers on postoperative pain after endodontic treatment in patient with irreversible pulpitis: A randomized controlled clinical trial study

Protocol summary

Study aim

• Post-treatment pain after AH26 and Resil sealer and comparison of patients' pain levels with AH26 sealer and Resil sealer. • Analgesics consumption after endodontic treatment with AH26 and Resil sealer. • Comparison of analgesics consumption after endodontic treatment with AH26 sealer and Resil sealer.

Design

A clinical trial with a control group, with parallel groups, double-blind, randomized by stratified permuted block randomization method, phase 3 per 100 patients

Settings and conduct

Patients will be selected from those referred to the endodontics department of Shahid Beheshti Dental School who have first or second mandibular molars with irreversible pulpitis. Participants were divided into two groups based on the type of sealer used and the pulp condition: 1) irreversible pulp/sealer AH26 2) irreversible pulp / Resil sealer and 50 patients will be examined in each group. It is a double-blind controlled randomized trial. Patients are randomly assigned to the modified block randomization method.

Participants/Inclusion and exclusion criteria

Individuals who have molars with irreversible pulpitis will be selected. Patients with healthy periapical tissue and without allergic sensitivity to the materials and drugs used during endodontic treatment are included in the study. Patients who need emergency treatment or have taken painkillers and antibiotics during the last seven days with more than 4 mm probing depth are excluded from the study.

Intervention groups

The AH26 resin sealer is placed in the canals for obturation in the first group. The Resil resin sealer is placed in the canals for obturation in the second group.

Main outcome variables

Number of pain after root canal treatment; Number of analgesic consumption

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150720023253N5**
Registration date: **2022-05-10, 1401/02/20**
Registration timing: **registered_while_recruiting**

Last update: **2022-05-10, 1401/02/20**
Update count: **0**

Registration date

2022-05-10, 1401/02/20

Registrant information

Name
Nazanin Zargar
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Country
Iran (Islamic Republic of)
Phone
+98 21 2240 3075
Email address
n.zargar48@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-05-10, 1401/02/20

Expected recruitment end date

2022-06-10, 1401/03/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of AH26 and Resil resin sealers on postoperative pain after endodontic treatment in patient with irreversible pulpitis: A randomized controlled clinical trial study

Public title

The effect of AH26 and Resil sealers on pain after endodontic treatment

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients aged 18 to 60 years Patients who do not have systemic problems and immunosuppression and are not treated with medication. Patients who are not allergic to the medicines used during endodontic treatment and local anesthetics. Patients with a long-term positive pulp response to the cold test and EPT (moderate to severe responses (vas = 40-100)) or long and delayed responses. Patients diagnosed with irreversible pulpitis in the first or second mandibular molars. Patients with healthy periapical tissue (confirmed by radiography and clinic)

Exclusion criteria:

Symptomatic teeth that need emergency endodontic treatment. Teeth that have been treated in two sessions. Patients who have been taking analgesics or antibiotics for the past seven days. Patients with periodontal disease (probe depths greater than 4 mm). Teeth with open apex, apical resorption, or canal calcification. Patients who have multiple teeth in need of endodontic treatment. Teeth that have been treated with crown. Patients taking antibiotics after treatment for any reason. Patients with allergies to nonsteroidal anti-inflammatory drugs Patients who are pregnant or breastfeeding. Overfilling treatments (gutta-percha or sealer extrusion beyond radiographic apex). Under filing treatments (more than 2 mm shorter than radiographic apex). Teeth with severe crown destruction need core build-up crowns.

Age

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

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

The permuted block randomization method randomly divides 100 patients into two groups. Eighteen blocks, each with four subjects, are assumed. The statistician generates the random sequence for each block using the Excel software (Microsoft Corporation, Redmond, WA, USA). Following the random sequence, a nurse places the sealer and VAS diagrams into similar opaque bags labeled for each block and opens only after chemo-mechanical preparation and before the obturation. The investigator is unaware of the coding details.

Blinding (investigator's opinion)

Double blinded

Blinding description

A research assistant not involved in the treatment performs allocation by random permuted block and stratification by gender. Computer-generated randomized patient codes concealed in opaque envelopes are revealed just before obturation. The envelopes are opened by an assistant not involved in the research, but only when the endodontic sealer is going to be inserted into the root canal. Patients are randomized for the endodontic sealer used (AH26, Resil). Each patient can contribute a maximum of two teeth only when they are on opposite sides of the mouth. Patients are blinded to the treatment allocation, and clinicians are also blinded to the treatment allocation up to obturation. The operator knows which sealer will be used right before filling the root canal. The patients are blinded to the sealer.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Shahid Beheshti University of Medical Sciences, School of Dentistry

Street address

Shahid Beheshti University of Medical Sciences., Daneshjou Blvd., Velenjak., Tehran

City

Tehran

Province

Tehran

Postal code

1983963113

Approval date

2021-12-26, 1400/10/05

Ethics committee reference number

IR.SBMU.DRC.REC.1400.088

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
Number of pain after root canal treatment
Timepoint
6,12,24,48 hours after treatment and 3,4,5,6 and 7 days after treatment
Method of measurement
visual analog scale

2

Description
Dosage of analgesics consumption
Timepoint
6,12,24,48 hours after treatment and 3,4,5,6 and 7 days after treatment
Method of measurement
Number of medicaments taken

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: After canal preparation and selecting the gutta-percha cone, the AH26 resin sealer is placed in the canals for obturation.
Category
Treatment - Drugs

2

Description
Intervention group: After canal preparation and selecting the gutta-percha cone, the Resil resin sealer is placed in the canals for obturation.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Beheshti University of Medical Sciences, School of Dentistry
Full name of responsible person
Dr. Nazanin Zargar
Street address
Endodontics Department., Shahid Beheshti Dental school., Daneshjou Blvd., Velenjak
City
Tehran
Province
Tehran
Postal code
1983969411
Phone
+98 21 2240 3075
Email
N.zargar48@yahoo.com
Web page address
http://www.dentistry.sbmu.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Dr.zarghi
Street address
Shahid Beheshti University of Medical Sciences., Daneshjou Blvd., Velenjak., Tehran
City
Tehran
Province
Tehran
Postal code
1983963113
Phone
+98 21 2243 9780
Email
zarghi@sbmu.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shahid Beheshti 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
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Dr. Nazanin Zargar

Position
Assistant Professor

Latest degree
Specialist

Other areas of specialty/work
Dentistry

Street address
Shahid Beheshti University of Medical Sciences., Daneshjou Blvd., Velenjak., Tehran

City
Tehran

Province
Tehran

Postal code
1983963113

Phone
+98 21 2217 5350

Email
nzargar48@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Dr. Nazanin Zargar

Position
Assistant Professor

Latest degree
Specialist

Other areas of specialty/work
Dentistry

Street address
Shahid Beheshti University of Medical Sciences., Daneshjou Blvd., Velenjak., Tehran

City
Tehran

Province
Tehran

Postal code
1983963113

Phone
+98 21 2217 5350

Email
nzargar@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Dr. Nazanin Zargar

Position
Assistant Professor

Latest degree
Specialist

Other areas of specialty/work
Dentistry

Street address
Shahid Beheshti University of Medical Sciences., Daneshjou Blvd., Velenjak., Tehran

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Province
Tehran

Postal code
1983963113

Phone
+98 21 2217 5350

Email
nzargar48@yahoo.com

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