ISRCTN42633118 https://doi.org/10.1186/ISRCTN42633118

Comparative study of postoperative pain and healing capacity of two endodontic sealers (AH Plus and NeoSealer Flo)

Submission date
29/01/2025

Recruitment status
No longer recruiting

Registration date
18/02/2025

Overall study status
Completed

Last Edited
06/03/2025

Condition category
Oral Health

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
This study focuses on apical periodontitis, a common inflammation that can occur when root canal treatments fail. The success of these treatments depends on how well the root canal is sealed. Bioceramic sealants like Neosealer Flo might help improve healing because they are compatible with the body and release calcium ions. The study aims to compare two sealants, AH Plus and Neosealer Flo, in terms of pain after treatment, seal quality, and healing.

Who can participate?
Adults who need root canal treatment and are in good general health can participate in this study.

What does the study involve?
Participants will be randomly assigned to receive either the AH Plus or Neosealer Flo sealant during their root canal treatment. They will be asked to rate their pain at 24 and 48 hours, and again at 7 days after the treatment. The quality of the seal and healing will be checked after 6 months through clinical and radiographic evaluations.

What are the possible benefits and risks of participating?
Participants may benefit from improved healing if the new sealant proves to be more effective. However, there are risks of experiencing pain or discomfort after the treatment, as with any dental procedure.

Where is the study run from?
Centre for Dental Innovation and Specialities of the Universidad Alfonso X el Sabio (Spain)

When is the study starting and how long is it expected to run for?
The study starts in January 2024 and is expected to run until December 2024.

Who is funding the study?
Fundacion Banco de Santander (Spain)

Who is the main contact?
Dr Juan Algar Pinilla, jalgapin@uax.es

Contact information

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Scientific, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
1.016.017

Study information

Scientific Title
Randomised clinical trial: Effect of AH Plus and Neosealer Flo on postoperative pain and healing of periapical lesions

Acronym
ECA AH VS. NEO

Study objectives
H0: There are no statistically significant differences in postoperative pain and healing capacity between the sealers.
H1: There are statistically significant differences between the two.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 14/03/2024, Bioethics Committee of the Universidad Alfonso X el Sabio (C. de Emilio Muñoz, 13, Madrid, 28691, Spain; +34 913273262; investigacion@uax.es), ref: 2024_3/256

Study design
Interventional single-blind randomized clinical trial

Primary study design
Interventional

Study type(s)
Treatment, Efficacy

Health condition(s) or problem(s) studied
Root canal treatment

Interventions
Patients will be treated at the Centre for Dental Innovation and Specialities of Universidad Alfonso X el Sabio, Madrid, Spain. Participants will be randomly assigned into two groups using the online tool random.org: the AH group (treated with AH Plus) and the NEO group (treated with Neosealer Flo). Both operators and patients will remain blinded to the allocated sealer until the obturation phase.

Local anesthesia will be administered with 4% articaine and epinephrine to ensure a pain-free and stable working field. The surgical field will be isolated using a rubber dam to minimize contamination and protect soft tissues. Pre-endodontic composite restorations will be placed if necessary to prevent leakage.

After caries removal, the pulp chamber will be opened, and root canal orifices located under magnification. Pre-flaring will be performed, and the working length determined with an electronic apex locator and verified radiographically. Root canal instrumentation will proceed

with rotary files (Endogal system), alternating with irrigation using 2.5% sodium hypochlorite. Final irrigation will include ultrasonic activation of sodium hypochlorite and a 17% EDTA rinse to remove the smear layer.

Obturation will be performed using the vertical compression technique with the allocated sealer. A heated carrier will compact the gutta-percha, and the coronal two-thirds of the canal will be filled with injectable gutta-percha. The canal entrance will be sealed with flowable composite and temporary material. Radiographs will assess obturation quality, ensuring no voids and a final fill within 2 mm of the radiographic apex.

Postoperative pain will be assessed using the Numerical Rating Scale (NRS) at baseline, 24, and 48 hours, with patients documenting analgesic use. A 7-day follow-up will include pain reassessment and placement of the final coronal restoration.

Clinical and radiographic follow-ups will occur at 6 months to evaluate treatment success. Success will be defined by the absence of clinical symptoms (e.g., pain, inflammation) and radiographic signs of failure, in accordance with AAE criteria.

Intervention Type
Procedure/Surgery

Primary outcome(s)
1. Postoperative pain is measured using Visual Analog Scale (VAS) at baseline (prior to treatment), 24 hours postoperative, 48 hours postoperative, and 72 hours postoperative
2. State of the lesion is measured using preoperative radiograph at the diagnostic phase and at the 6 month follow-up

Key secondary outcome(s))
1. Cementum extrusion is measured using visual inspection at the final radiograph of the endodontic treatment

Completion date
31/12/2024

Eligibility

Key inclusion criteria
1. Patients over 18 years of age, cooperative and in good general health (ASA class I or II).
2. Have at least one tooth requiring endodontic treatment and provide informed consent for both the treatment and study participation.
3. The resulting RCTs will have to meet the following criteria:
3.1. Root canal obturation within 2 mm of the radiographic apex.
3.2. Absence of voids on the final radiograph.

Participant type(s)
Healthy volunteer, Patient

Healthy volunteers allowed
No

Age group

Adult

Lower age limit
18 years

Upper age limit
100 years

Sex
All

Total final enrolment
70

Key exclusion criteria
1. Teeth with open apices.
2. Coronal cracks extending into the root canal.
3. Root perforations.
4. Severe periodontal disease.
5. Vertical root fractures.

Date of first enrolment
14/03/2024

Date of final enrolment
30/06/2024

Locations

Countries of recruitment
Spain

Study participating centre
Centre for Dental Innovation and Specialities of the Universidad Alfonso X el Sabio
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Study participating centre
Instituto de Postgrados Avanzados Odontológicos
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Sponsor information

Organisation
University Alfonso X el sabio

Funder(s)

Funder type
Industry

Funder Name
Fundación Banco Santander

Alternative Name(s)
Banco Santander Foundation, Santander Fundación, FBS

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
Spain

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request from (Dr. Juan Algar Pinilla jalgapin@uax.es)

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet			17/02/2025	No	Yes