

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	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 18/02/2025	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 06/03/2025	Condition category Oral Health	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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

Type(s)

Scientific, Principal investigator

Contact name

Prof Juan Algar

ORCID ID

<https://orcid.org/0000-0002-3616-3210>

Contact details

Universidad Alfonso X el Sabio, C. de Emilio Muñoz, 13
Madrid
Spain
28691
+34 913273262
jalgapin@uax.es

Type(s)

Public

Contact name

Prof Juan Manuel Aragonese Llamas

ORCID ID

<https://orcid.org/0000-0003-0187-4992>

Contact details

Universidad Alfonso X el Sabio, C. de Emilio Muñoz, 13
Madrid
Spain
28691
+34 913273262
jaraglam@uax.es

Additional identifiers

Clinical Trials Information System (CTIS)

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

C. de Emilio Muñoz, 13

Madrid

Spain

28691

Study participating centre

Instituto de Postgrados Avanzados Odontológicos

Avenida Ciudad De Barcelona, 103

Madrid

Spain

28007

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