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Root canal treatment outcomes using different ways to clean and disinfect teeth, including light technology (LASER)

Submission date 26/03/2025	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 08/04/2025	**Overall study status** Ongoing	[_] Statistical analysis plan [_] Results
Last Edited 02/05/2025	**Condition category** Oral Health	[_] Individual participant data [X] Record updated in last year

Plain English summary of protocol

Background and study aims
This clinical study aims to understand if the effectiveness of root canal treatment, a common dental procedure to save infected teeth, can be enhanced. The goal is to compare different methods of existing root canal disinfection protocols, with the aim of improving the overall success of the treatment.

Who can participate?
All adult patients who are able to provide consent to have root canal treatment of their tooth with root canal infection.

What does the study involve?
For participants, this study involves undergoing root canal treatment as required for their dental condition. The crucial aspect of the study is the comparison of different techniques used to clean and disinfect the inside of the tooth's root canals during this treatment.
Root canal treatment as already planned and consented for.
The treatment will be the standard of care except for one specific part: the way the disinfectant (irrigant) is activated within the root canals at the end of the cleaning process.
Patients will be randomly allocated to one of three groups, each receiving a different method of irrigant activation:
-Manual agitation
-Sonic activation
-LASER activation

This irrigant activation step will typically last for 1 to 2 minutes per root canal.

Patients will need to attend five visits in total:
1. Initial assessment and consent
2. Treatment

3. 2-week review
4. 1-year review
5. 2-year review

Anonymised information about the patients' root canal treatment and anonymised radiographs will be sent to researchers at the University of Central Lancashire for analysis. No identifiable data will be sent outside of the patients' dental practice

Participation is entirely voluntary, and patients can withdraw at any time without giving a reason and without it affecting the standard of care they receive

What are the possible benefits and risks of participating?
There are no additional risks involved in taking part in the study beyond those associated with standard root canal treatment.

There is no direct benefit for participating, but the study aims to improve the understanding and future success of root canal treatments for other patients.

At the end of the treatment and at each review, patients will be informed of any problems encountered and the outcome of your treatment. If the root canal treatment is deemed to have failed, the research team will provide the same treatment as the standard of care (root canal re-treatment, extraction, or endodontic microsurgery).

Where is the study run from?
University of Central Lancashire (UK)

When is the study starting and how long is it expected to run for?
January 2023 to December 2027

Who is funding the study?
DentsplySirona has loaned investigators sonic activator (Endoactivator).

Who is the main contact?
Professor Shanon Patel, shanon.patel1@gstt.nhs.uk

Contact information

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Scientific, Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
DENT10202302

Study information

Scientific Title
Outcome of non-surgical endodontic treatment using different irrigant activation techniques

Acronym
TuLe

Study objectives
There is no difference in outcome of non-surgical endodontic treatment using different irrigant activation techniques (GP pumping, Sonic activation and Laser activation)

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 04/01/2023, SoMD Ethics Review Panel (University of Central Lancashire, Preston, PR1 2HE, United Kingdom; -; some@uclan.ac.uk), ref: DENT10202302

Study design
Interventional randomized parallel trial

Primary study design
Interventional

Secondary study design
Randomised parallel trial

Study setting(s)
Dental clinic

Study type(s)
Quality of life, Efficacy

Participant information sheet
Not available in web format, please use the contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Healing of apical periodontitis (due to primary endodontic infection)

Interventions
Patients with root canal disease (also known as pathology of endodontic origin) who meet the inclusion criteria and not the exclusion criteria will be randomly allocated to one of three groups. The endodontic treatment for all groups will follow the standard of care in all stages, except for the method of activation of the irrigant. The irrigant activation will typically last 1 to 2 minutes per root canal at the end of the mechanical preparation. The three study arms are:
- Manual agitation: This group will receive the standard method of irrigant activation, involving hand agitation or gutta-percha pumping.
- Sonic activation: In this group, a sonic device will be used to activate the irrigant within the root

canals.
- LASER activation: This group will have their irrigant activated using laser light with Waterlase

Total Duration of Treatment and Follow-up:
The study is expected to span over a period of 3 years. Participants will attend 5 visits as part of the study.
1. Initial assessment and consent: This visit determines eligibility and provides study information.
2. Treatment: The assigned irrigant activation technique will be performed during the root canal treatment.
3. 2-weeks review: This appointment/phone review assesses the initial response and any immediate effects (post-op pain).
4. 1-year review: A follow-up appointment to evaluate the medium-term results of the treatment. Clinical and radiographic review using periapical radiographs and CBCT
5. 2-year review: The final follow-up to determine the sustained success of the different treatment methods. Clinical and radiographic review using periapical radiographs and CBCT
Clinical and radiographic assessments will be conducted at baseline (initial assessment), 12 months, and 24 months post-operatively.

Details of the Randomisation Process: Patients will be randomly allocated to one of the three study groups (Manual agitation, Sonic activation, LASER activation) after being assessed clinically and radiographically using an online tool (random.org)

Intervention Type
Device

Pharmaceutical study type(s)
Not Applicable

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Sonic activation (Endoactivator, DentsplySirona,, Charlotte, North Carolina, USA) and laser activation using Waterlase (BIOLASE, Megagen,Seoul, Korea).

Primary outcome measure
Healing outcome after non-surgical treatment measured using clinical examination (intact restoration, no fistulas or swelling, no mobility of the teeth or tenderness to percussion) and radiographical assessment using periapical radiographs and CBCT (absence or reduction of any radiolucencies or widening of the periodontal ligament space and vertical or horizontal fractures and absence of external root resorption) at 12 months and 24 months

Secondary outcome measures
1. Patient self-reported pain measured using VAS (Visual Analogue Scale) pre-operatively, and then day 1, 3, 5, 7 and 14 following the treatment
2. Patients' quality of life measured using OHIP-14 preoperatively and at year 1 and year 2

Overall study start date
04/01/2023

Completion date

31/12/2027

Eligibility

Key inclusion criteria
1. Patients either male or female over the age of 18 (who can consent for themselves) in good general health
2. Patients with clinical symptoms of pathology of endodontic origin who need endodontic treatment
3. All anterior and posterior teeth included in study

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
90 Years

Sex
Both

Target number of participants
264

Key exclusion criteria
1. External or internal root resorption
2. Pregnant women, in view of requirements for radiographs.
3. Patients younger than 18 years.
4. Patients unable to give consent.
5. Patients who have been administered antibiotics in the previous month.
6. Immunocompromised patients.

Date of first enrolment
10/01/2023

Date of final enrolment
31/05/2025

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University of Central Lancashire
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Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Funder Name
DentsplySirona

Results and Publications

Publication and dissemination plan
Planned publication in a peer reviewed journal

Intention to publish date
10/12/2027

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study will be published as a supplement to the results publication

IPD sharing plan summary
Published as a supplement to the results publication