ISRCTN16553016 https://doi.org/10.1186/ISRCTN16553016

A study comparing treatments for severe toothache in adult teeth: Full Pulpotomy or Root Canal Treatment

Submission date
20/03/2023

Recruitment status
No longer recruiting

Registration date
12/07/2023

Overall study status
Ongoing

Last Edited
12/07/2023

Condition category
Oral Health

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

Plain English summary of protocol

Background and study aims
Tooth decay is very common; almost all adults have some decay in their back teeth. Treating decay costs the NHS over £3.4 billion each year. Where the tooth decay has spread deep into the nerve, and caused irreversible damage, there are different treatments available. The most common treatments are to take out the tooth or use Root Canal Treatment. Root Canal Treatment removes all the nerve and is very expensive, time consuming and technically demanding. A possible alternative is to remove only the infected part of the nerve, which is an easier and quicker treatment. This technique is called Pulpotomy.
Research has already been conducted in children's teeth that supports using pulpotomy instead of Root Canal Treatment. However, there are gaps in our knowledge about using Pulpotomy in adult's teeth.
The aim of this study is to compare Pulpotomy with root canal treatment in adult patients. We will consider the pain experienced by patients, the impact of treatment on their lives, whether further treatment is needed due to infection and the time and financial costs incurred.

Who can participate?
NHS adult (16 years or older) dental patients who have irreversible damage of the nerve of a tooth in adult back teeth and who agree to take part.

What does the study involve?
Participants will be randomly allocated to receive one of the two treatments (Root Canal Treatment or Pulpotomy).
We will measure how well the treatments work over one year. We will look for evidence of treatment success and compare symptoms such or swelling. We will measure if the tooth needs further treatment, for example, a new or repeat Root Canal Treatment or if the tooth needs to be extracted. We will also measure patients' pain and anxiety, how their oral health affects their quality of life, treatment costs and satisfaction with their dental treatment.
We will use patient questionnaire surveys, X-rays and data from dentists to evaluate the success of the two treatments. We will also interview dental staff and patients about their views on the two treatments.

What are the possible benefits and risks of participating?
Root Canal Treatment is the standard procedure used by dentists to treat Irreversible Pulpitis, but in some cases, the Full Pulpotomy Treatment may be quicker and less invasive than Root Canal Treatment. Both treatments are an alternative to having an extraction. As with all treatments, whichever treatment participants have, there is a small risk that it may not work, and further treatment may be required. Further treatment for Full Pulpotomy could be a Root Canal Treatment or having the tooth removed. Both treatments include having X-rays taken. This is part of routine care. Dental radiographs need very low doses of radiation and are equivalent to less than a day of background radiation. We do not think that there are any possible disadvantages for those that this treatment is suitable for, as they will require some form of treatment for the condition.

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

When is the study starting and how long is it expected to run for?
June 2020 to December 2025

Who is funding the study?
The National Institute for Health Research (NIHR) Health Technology Assessment (HTA) Programme (UK)

Who is the main contact?
Lori Brown, Study Administrator
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Study website
https://w3.abdn.ac.uk/hsru/PIP/Public/Public/index.cshtml

Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
323138

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
IRAS 323138, Sponsor ID 2-054-22, CPMS 56091

Study information

Scientific Title
Pulpotomy or root canal treatment for the management of irreversible pulpitis in mature teeth

Acronym
PIP Study

Study objectives
Tooth decay is very common; almost all adults have some decay in their back teeth. This costs the NHS over £3.4 billion each year. Where tooth decay has spread deep into the nerve, and caused serious and irreversible damage, there are different treatments available. The most common treatments are to take out the tooth or have root canal treatment (RCTx). RCTx removes all the nerve, is expensive, time consuming and technically demanding. A possible alternative is to remove only the infected part of the nerve, which could be an easier and quicker treatment. This is called pulpotomy.
Research in children's teeth supports using pulpotomy instead of root canal treatment. However, there are gaps in our knowledge about using pulpotomy in adult teeth. Following a feasibility study, the PIP Study aims to provide this knowledge.
The PIP Study compares pulpotomy with root canal treatment in adult patients.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 13/06/2023, West Midlands - Coventry & Warwickshire Research Ethics Committee (The Old Chapel, Royal Standard Place, Nottingham, NG1 6FS, United Kingdom; +44 207 104 8013; coventryandwarwick.rec@hra.nhs.uk), ref: 23/WM/0094

Study design
Interventional randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Dental clinic

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Pulpotomy or root canal treatment for the management of irreversible pulpitis in mature teeth

Interventions
We will recruit 530 NHS adult dental patients who have irreversible damage of the nerve in a suitable tooth who agree to take part. They will receive one of the two treatments (Root Canal Treatment or Full Pulpotomy) at random, using a computerised randomisation tool that dentists will access using the online study database.

Root Canal Treatment is the current treatment available on the NHS to try and save your tooth. It aims to removes all of the nerve from the tooth and replaces it with a filling material. An alternative treatment for this kind of toothache is called a Full Pulpotomy. A Full Pulpotomy removes only the top portion of the nerve which includes the damaged part caused by decay but aims to keep the lower (healthy) portion alive. Full Pulpotomy is already used on children's teeth and on adult teeth when they are being treated in dental hospitals. However, it is not yet routinely used on adult teeth in NHS dental practices.

The treatments will take a varying amount of time to complete depending on individual circumstances, however a Full Pulpotomy usually takes 1-2 appointments and a Root Canal Treatment can take 3-4 appointments. The duration of the appointment will vary.

We will measure how well the treatments work over one year, with participant questionnaires completed at baseline, 7 days and also at 12 months. We will look at treatment success, levels of pain and if the tooth needs more treatment using CRFs as well as the questionnaires. We will measure patients' anxiety, how their oral health affects their quality of life, treatment costs and satisfaction. X-rays taken at baseline, after treatment and at 12-months along with data from dentists to compare the two treatments. We will also interview dental staff and patients.

Intervention Type
Procedure/Surgery

Primary outcome measure
1. Clinical success of Full Pulpotomy with Root Canal Treatment (no re-intervention or symptoms of pulpitis or apical periodontitis) at 1 year. Assessed using radiograph at 1-year post-randomisation: Success is the absence of apical radiolucency in the periapical radiograph following participant's initial intervention
2. Pain is measured using the 10-point visual analogue score (VAS) at baseline, 7 days and 12 months
3. Oral Health Related Quality of Life will be assessed at 7 days and 1 year using the Oral Health Impact Profile 14 (OHIP-14)
4. Health status will be assessed using the generic EQ5D at 7 days and 1 year, consisting of five

dimensions of HRQoL
5. Dental anxiety will be assessed using the validated MDAS criteria at 1 year
6. Patient Satisfaction will be assessed using the NHS England Commissioning of Dental Services Guidelines Patient Reported Experience Measures (PREMs) at 1 year

Secondary outcome measures
1. Radiographic success (absence of radiolucency in participant's initial intervention)
2. Patient health related quality of life (OHIP-14) at 1 year
3. Dental pain (10-point visual analogue score (VAS)) at 1 year
4. Dental anxiety (assessed using the validated MDAS criteria) at 1 year
5. Satisfaction with care/treatment and adverse events at 1 year in 12-month questionnaire and 12 month follow up CRF
6. Patient health related quality of life and dental pain at 7 days measured using VAS and OHIP-14 in 7-day questionnaire
7. General population preferences for treatment and outcomes and predict uptake, NHS and patient perspective costs; incremental net benefit over the study follow up; and incremental cost per QALY over the 1-year follow-up and extrapolated over a modelled lifetime horizon, measured using the 12-month questionnaire, follow up CRF at 12-months and participant interviews.
8. To explore the implementation of technologies and the mechanisms of impact including acceptability of interventions to patients and clinicians by interviews at 1 year

Overall study start date
01/06/2020

Completion date
31/12/2025

Eligibility

Key inclusion criteria
Adults (16 years and older) with symptoms indicative of irreversible pulpitis (as defined by the European Society of Endodontology) in a premolar or molar tooth with deep caries and or a deep restoration.

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
530

Key exclusion criteria
1. Tooth with immature roots, clinical or radiographic signs of a necrotic pulp, or a poor prognosis (e.g., internal or external resorption)

2. Presence of a sinus, tenderness to percussion, buccal tenderness, pathological mobility or evidence of pathology on a periapical radiograph
3. Insufficient tooth tissue for a restoration
4. All treatment delivered under a private contract

Date of first enrolment
01/05/2023

Date of final enrolment
31/10/2024

Locations

Countries of recruitment
England

Scotland

United Kingdom

Study participating centre
Dundee Dental Hospital & Research School
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Sponsor information

Organisation
University of Dundee

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Tayside Medical Science Centre
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Sponsor type
University/education

Website
http://www.dundee.ac.uk/

ROR
https://ror.org/03h2bxq36

Funder(s)

Funder type
Government

Funder Name
Health Technology Assessment Programme

Alternative Name(s)
NIHR Health Technology Assessment Programme, HTA

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal

Intention to publish date
01/01/2025

Individual participant data (IPD) sharing plan
The data-sharing plans for the current study are unknown and will be available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date