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Traditional root canal or minimally invasive pulpotomy treatment for managing painful carious teeth in general dental practice

Submission date
05/08/2021

Recruitment status
No longer recruiting

Registration date
17/08/2021

Overall study status
Completed

Last Edited
22/11/2023

Condition category
Oral Health

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

Plain English summary of protocol

Background and study aims
When a tooth is decayed and has a deep cavity, the nerve of the tooth (the dental pulp) can become infected and inflamed. This can be very painful and the pulp needs to be treated to ease the pain. Teeth with infected pulps are traditionally treated by conventional root canal treatment (RCTx). This involves removing the damaged area of the tooth including the entire dental pulp, cleaning, disinfecting and sealing the root canal before placing a filling in the crown of the tooth. Root canal treatment is a technically difficult procedure to carry out particularly in teeth at the back of the mouth. It often requires several visits to the dentist to be completed, is destructive to the tooth and is expensive for patients. One of the alternatives is called pulpotomy, which is a simpler, less expensive procedure performed in a single visit. Pulpotomy aims to remove only a portion of the infected nerve tissue, thereby keeping the tooth alive. Complete pulpotomy (Cp) involves the removal of all of the infected nerve tissue in the crown of the tooth leaving the pulp in the root intact. The pulp is then sealed with a material that aids healing before the placement of the final filling. Whether or not pulpotomy is successful depends in part on the dentist knowing that the tooth is suitable for the procedure. Currently dentists use pain symptoms as a guide to diagnosis and if the patient reports continuous pain then the dentist assumes that the whole pulp is inflamed and carries out RCTx. Pain is subjective as people differ in the way they report pain. The presence of pain alone would not inform the dentist whether the whole or part of the pulp is inflamed. When the pulp becomes inflamed, it produces proteins, which suggest the presence of inflammation, so testing for these proteins may help dentists know the degree of inflammation in the pulp and subsequently decide whether to offer complete pulpotomy or root canal treatment. This study will investigate if pulpotomy is as clinically and cost-effective as root canal treatment for treating infected tooth pulps in general dental practices in Northern Ireland (NI). The researchers will also measure inflammatory proteins found in infected dental pulp tissue to determine if their concentration can be used to make a diagnosis and decide on the best treatment for a patient.

Who can participate?
General dental practice patients aged 18 years and older who have pain in a permanent back tooth from an infected nerve

What does the study involve?
Participants will be randomly allocated to receive one of two treatments to relieve their dental pain - the current standard of care, root canal treatment or complete pulpotomy. The patient will complete a pain diary recording their experience of pain on days 3 and 7 after the procedure and will be assessed clinically and radiographically 12 months after completion of the procedure. Patients will also complete a short questionnaire about their experience of receiving care and will be invited to put a monetary value on the treatment. A laboratory analysis will be conducted on pulp tissue samples collected at the time of the procedure. Any relationship between the amount of inflammatory proteins present in the tissue sample and the outcome of the treatment will be investigated.

What are the possible benefits and risks of participating?
This is is a low-risk study. Complete pulpotomy forms the first stage of traditional root canal treatment so it is not a new procedure to dentists. Patients will have the opportunity to have their dental pain managed in a more conservative way that is both simpler and quicker to complete than the current standard of care. There is a small risk that treatment may not fully resolve the patient's symptoms and more treatment may be required.

Where is the study run from?
Queen's University Belfast (UK)

When is the study starting and how long is it expected to run for?
February 2020 to April 2024

Who is funding the study?
The study is funded by the Health and Social Care Research & Development Division, Public Health Agency, Northern Ireland (UK)

Who is the main contact?
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Contact information

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
292497

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
IRAS 292497

Study information

Scientific Title
TRaditional or minimally invasive Endodontics FOr managing caRious teeth with syMptomatic pulpitis- a pragmatic randomised trial in general dental practice in Northern Ireland

Acronym
REFORM

Study objectives

There is no difference in the clinical and or radiographic outcome and the cost effectiveness of treatment for teeth diagnosed as irreversibly inflamed and managed by traditional root canal treatment or complete pulpotomy.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 09/06/2021, Office for Research Ethics Committees Northern Ireland (ORECNI) (Customer Care and Performance Directorate, Unit 5, Tissue Industrial Estate West, Rathdown Walk, Moira Road, Lisburn BT28 2RF UK; +44 (0)2895361400; RECA@hscni.net), ref: 21/NI/0078

Study design
Multi-site interventional single-blinded randomized controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Conservative treatment of irreversible pulpitis in adult patients in pre/molar teeth

Interventions
164 patients aged 18 years or older with a diagnosis of irreversible pulpitis affecting a permanent posterior tooth will be randomised to one of two treatment arms- traditional root canal treatment or Biodentine complete pulpotomy. Randomisation will be by sealed opaque envelopes using a block randomisation system. Follow up is for 12 months.

Intervention Type
Procedure/Surgery

Primary outcome(s)
Success or failure of the composite outcome measure at 12 months. Success will be defined as achieving all three criteria and failure of any single criteria within the composite will indicate a treatment failure: absence of pain, absence of swelling or sinus around the tooth indicative of acute or chronic periapical infection, no evidence of periapical radiolucency or internal root resorption confirmed by history, clinical examination and radiographic assessment.

Key secondary outcome(s))
1. Absence of pain measured using a numeric rating scale (NRS) on days 3 and 7 postoperatively
2. Structural integrity of tooth defined as an intact, non-defective restoration at 12 months
3. No further interventions or adverse events using patient records during the 12-month follow-up period
4. A health economic evaluation to include incremental cost-effectiveness analysis at 12 months
5. Process evaluation (patients' and practitioners' satisfaction with the procedure) and identification of facilitators and barriers over 12 months
6. Concentration of inflammatory biomarkers collected from infected pulp tissue samples and measured using ELISA at baseline

Completion date
30/09/2024

Eligibility

Key inclusion criteria
1. Patients 18 years or older with symptoms of irreversible pulpitis affecting a permanent posterior tooth. Symptomatic irreversible pulpitis may include sharp pain upon thermal stimulus, lingering pain, spontaneity (unprovoked pain) and referred pain (AAE 2017)
2. Tooth should be responsive to sensibility tests
3. Tooth should be restorable and can be adequately isolated during treatment

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Teeth with active periodontal disease (pocket depth >5 mm)
2. Participants with complex medical histories that may affect their caries experience and healing ability
3. Inability to provide consent
4. History of trauma to tooth
5. Presence of apical radiolucency or ligament enlargement on radiograph
6. Pregnant or breast-feeding patient

Date of first enrolment
23/09/2021

Date of final enrolment
31/05/2024

Locations

Countries of recruitment
United Kingdom

Study participating centre

General dental practices - specific practices not confirmed at time of registration
Northern Ireland
United Kingdom
-

Sponsor information

Organisation
Queen's University Belfast

ROR
https://ror.org/00hswnk62

Funder(s)

Funder type
Government

Funder Name
Public Health Agency

Alternative Name(s)
Public Health Agency (PHA), Public Health Agency (Northern Ireland), HSC Public Health Agency, publichealthni, PHA

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
Participant-level data will be made available within 24 months of study completion. The data-sharing plans for the current study are unknown and will be made available at a later date.

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No
Participant information sheet	Participant information sheet version 1	11/11/2025	11/11/2025	No	Yes
Protocol file		14/04/2021	17/08/2021	No	No