ISRCTN76503940 https://doi.org/10.1186/ISRCTN76503940

Comparing complete and partial removal of decay in molar teeth

Submission date
04/10/2019

Recruitment status
No longer recruiting

Registration date
30/10/2019

Overall study status
Completed

Last Edited
10/03/2025

Condition category
Oral Health

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

Plain English summary of protocol

Background and study aims
Tooth decay is very common, with most teenagers and adults having some decay in their back teeth (molars). Treating tooth decay (dental caries) costs the NHS over £3.4 billion each year. There are different ways of treating decayed teeth where the decay has spread deep into the tooth close to the nerve. The most common way is to take away all of the decay before placing a filling in the tooth. This is known as complete decay removal. When removing all the decay there is a small chance of serious damage to the nerve. Such damage makes root canal treatment or tooth loss (extraction) likely. Also drilling the tooth to remove all the decay can weaken the tooth so it is more likely to break and need further treatment.
Dentists want to compare the complete removal of decay with a new way that does not remove all of the decay. In the new way, only some of the decay is removed and a filling is then put in to stop the decay from getting worse. This is known as selective decay removal. There is no chance that the nerve will be damaged when only some of the decay is taken out. If only some of the decay is taken out it is possible that the tooth will still need more treatment later. There is research in children's teeth that supports this new way. However, there are gaps in our knowledge about selective decay removal in adult teeth.
This study will test selective decay removal compared to complete decay removal to find out if follow-up treatment was needed, the costs of this follow-up, the pain experienced by the patients and the impact on their lives.

Who can participate?
People over 12 years old can participate if they have teeth that have deep decay which can be treated with a filling, and if this treatment would normally be done on the NHS.

What does the study involve?
Participants will be given one of the two treatments at random. They will be followed up as normal by their dentists with clinical information from routing follow-up visits to their dentist shared with the study team until the study closes in February 2024. Participants will be asked to complete a questionnaire about their health and their teeth when they start the study and again 1, 2, and 3 years afterwards.

What are the possible benefits and risks of participating?
Participants will receive treatment for their tooth decay and will be followed up for 3 years afterwards. Participants might not gain any additional benefit from taking part. However, they will be directly helping the study team to inform the treatment of future patients with deep tooth decay. The results of the study will help plan effective services offered by the NHS in the future.

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 2019 to April 2024

Who is funding the study?
National Institute for Health Research (UK)

Who is the main contact?
Professor Jan Clarkson, script@dundee.ac.uk

Study website
https://w3.abdn.ac.uk/hsru/script

Contact information

Type(s)
Public

Contact name
Ms Ruth Floate

Contact details
University of Dundee School of Dentistry
Park Place
Dundee
United Kingdom
DD1 4HN
+44 (0)1382 383818
r.floate@dundee.ac.uk

Type(s)
Scientific

Contact name
Prof Jan Clarkson

ORCID ID
http://orcid.org/0000-0001-5940-2926

Contact details
Dundee Dental School and Hospital, DHSRU
University of Dundee

Park Place
Dundee
United Kingdom
DD1 4HN
+44 (0)1382740990
j.e.clarkson@dundee.ac.uk

Type(s)
Public

Contact name
Prof Jan Clarkson

ORCID ID
http://orcid.org/0000-0001-5940-2926

Contact details
Dundee Dental School and Hospital, DHSRU
University of Dundee
Park Place
Dundee
United Kingdom
DD1 4HN
+44 (0)1382740990
script@dundee.ac.uk

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
HTA Project: 17/127/07

Study information

Scientific Title
Selective Caries Removal in Permanent Teeth (SCRiPT)

Acronym
SCRiPT

Study objectives

To compare clinical and cost-effectiveness of selective caries removal (SCR) compared to complete caries removal (CCR) in permanent teeth in NHS dental attenders aged 12 years and over who have deep caries in an adult pre-molar or molar tooth.

Ethics approval required
Old ethics approval format

Ethics approval(s)
To be submitted to North of Scotland Research Ethics Committee 1 or 2, or West of Scotland REC 4 or 5 in October or November 2019.

Study design
Pragmatic multi-centre single-masked two-arm randomized controlled trial including an internal pilot

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Prevention

Participant information sheet
The participant information sheet is not yet available.

Health condition(s) or problem(s) studied
Dental caries (decay)

Interventions
The interventions being evaluated, Selective Caries Removal (SCR) and the best alternative Complete Caries Removal (CCR) differ solely in the amount of carious dentine removed during the excavation phase of restorative treatment of deep dental caries. Dentists will restore the tooth with the material that they would normally use. This may be amalgam or resin composite with or without glass ionomer cement. Medicated material will not be used and information about any pulp protection material placed will be recorded.

Intervention: Selective caries removal (SCR)
The dentist will gain access to the dentine caries by removing superficial enamel or existing restoration. They will remove caries from the periphery of the cavity to allow for good adaptation and seal to the restoration either at the enamel dentine junction or the peripheral 2 mm of dentine if the cavity margin is on root dentine. The dentist will then remove remaining carious dentine to soft dentine, defined as dentine that deforms when an instrument is pressed into it and can be easily scooped up (e.g. with a spoon hand excavator) with little force being required.

Control: Complete caries removal (CCR)
The dentist will gain access to the dentine caries by removing enamel or existing restoration. They will remove caries to firm dentine defined as dentine that is physically resistant to hand excavation and some pressure needs to be exerted through an instrument to lift it.

Intervention Type
Procedure/Surgery

Primary outcome measure
Sustained tooth vitality will be assessed at routine dental visits, recorded in the CRF and used in a time-to-event framework defined as the time from randomisation to root canal treatment or extraction due to loss of vitality. The primary time point of interest is 3 years. Sustained tooth vitality will be determined by the absence of root canal treatment or extraction due to loss of vitality and the absence of clinical signs and symptoms of pulp death including evidence from radiographs.

Secondary outcome measures
Clinical:
1. Pulp exposure during caries removal measured following intervention with a yes/no answer in the case report forms asking "Was dental pulp tissue exposed/bleeding from the pulp observed?"
2. Progression of caries measured on examination at dental follow-up visits on a CRF question with a yes/no answer that asks "Was progression of caries identified through radiograph or clinical assessment?"
3. Tooth restoration failure and re-restoration measured on examination at dental follow-up visits or from routinely collected data before the end of the study by recording the treatment provided.

Patient-centred:
4. Dental pain measured using the 11-point Numerical Pain Rating Scale (NPRS-11) on participant questionnaires at baseline, 1, 2 and 3 years post-randomisation
5. Need for dental pain relief measured by asking “Did you take any dental pain relief medication?” on participant questionnaires at baseline, 1, 2 and 3 years post-randomisation
6. Health status measured using the EQ-5D-5L on participant questionnaires at baseline, 1, 2 and 3 years post-randomisation
7. Oral Health-Related Quality of Life measured using the short form Oral Health Impact Profile (OHIP-14) on participant questionnaires at baseline, 1, 2 and 3 years post-randomisation
8. Oral health behaviours measured using 4 non-standardised but previously used questions on participants questionnaires at baseline and 3 years post-randomisation
9. Patient satisfaction measured on participants questionnaires at 1-year post-randomisation using 3 satisfaction questions from NHS England commissioning of dental services guidelines and 1 general satisfaction question tailored to the trial intervention repeated at 1, 2 and 3 years post-randomisation

Economic outcomes measured over 3 years and modelled over a life time horizon:
10. NHS perspective on costs defined as intervention delivery costs (sourced from a dental practice completed CRF at baseline) and remaining follow up care, which will be sourced from the routine datasets and the treatment record forms
11. Patient perspective on costs measured using standard questions at 1, 2 and 3 years post-randomisation and in a subset of participants using a questionnaire about time and travel costs and co-payment for dental charges obtained from access to the centrally held routine data bases (NHS Scotland Information Services Division (ISD)/NHS Business Services Authority (BSA) etc.)

12. General population preferences measured using a separate discrete choice experiment (DCE) with a nationally representative sample of the UK general population.
13. Willingness to pay (WTP) - tariffs calculated from the DCE, and mapped to trial data to generate a measure of total WTP for each trial arm.
14. Incremental net benefits calculated as the difference between trial arms in terms of benefits (see WTP above) minus costs
15. Quality adjusted life years (QALY) derived from responses to the EQ-5D-5L (see Health status above) and valued using published general population tariffs.
16. Incremental cost per QALY is the difference in QALYs between groups divided by difference in costs.

Overall study start date
01/06/2019

Completion date
30/04/2024

Eligibility

Key inclusion criteria
1. Aged 12 years and over
2. Suitable to receive either clinical procedure
3. Receive some or all of their treatment under the NHS
4. One (or more) pre-molar or molar teeth with caries (primary or secondary) extending into the pulpal third of dentine
5. Caries may be proximal and/or occlusal and the lesion will be suitable for filling with a single restoration

Participant type(s)
Patient

Age group
Mixed

Lower age limit
12 Years

Sex
Both

Target number of participants
623

Key exclusion criteria
Carious tooth shows signs or symptoms of irreversible pulp pathology or loss of vitality including the presence of a sinus, tenderness to percussion, buccal tenderness, pathological mobility, severe sensitivity or evidence of pathology on a periapical radiograph

Date of first enrolment
01/02/2021

Date of final enrolment
30/09/2022

Locations

Countries of recruitment
Scotland

United Kingdom

Study participating centre
West End Dental Practice
243 Perth Road
Dundee
United Kingdom
DD2 1EL

Sponsor information

Organisation
University of Dundee

Sponsor details
Tayside Medical Science Centre
Ninewells Hospital & Medical School
Research & Development Office
Residency Block, Level 3
George Pirie Way,
Dundee
Scotland
United Kingdom
DD1 9SY
01382 383297
TASCgovernance@dundee.ac.uk

Sponsor type
University/education

Website
http://www.tasc-research.org

ROR
https://ror.org/03h2bxq36

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
The clinical trial report will be used for publication and presentation at scientific meetings. Investigators have the right to publish orally or in writing the results of the trial.
Summaries of results will also be made available to Investigators for dissemination within their clinical areas (where appropriate and according to their discretion).

The findings of the trial will be disseminated widely through professional, primary care, public and scientific routes. The results of the trial will be reported in high quality research outputs including the HTA Monograph, journal papers and conference presentations to dental, public health, policy and wider audiences. The results of the trial will be used to update Cochrane reviews and clinical guidelines as published by NICE, SIGN and Scottish Dental Clinical Effectiveness Programme and the online training resource will be made available to learning institutions across the UK. In addition it is hoped to produce a range of actionable knowledge tools to encourage implementation of the trial results. The cost effectiveness elements of SCRiPT and patient related outcomes will be of high importance to the NHS policy and decision makers, including the UK's four Chief Dental Officers and as such this trial has the potential to impact decision making for the general dental community both nationally and internationally. To enable this research to be embedded as an output and impact on future decision making we will draw on the extensive networks of the research team who are well connected, respected and cover a vast number of professional fields and demonstrate our ability to actively participate in creating a Global Evidence Ecosystem for Oral Health as aspired to by the MAGIC Project (30). Many of the research team members are part of the academic teaching community for both

undergraduate and postgraduate programmes. Through formal and informal channels and established teaching community networks, we will actively encourage Dental Schools to embed the research findings and clinical implications into teaching.

The results of the trial will be communicated directly to all participating dental practices who will be invited to attend the SCRiPT conference to showcase the results and work done by the practitioners involved. We will speak at national conferences for GDP's such as the British Dental Association conference, meetings and conferences of the Faculty of General Dental Practitioners and local practitioner meetings. We will continue our successful approach of including participating practitioners to speak at meetings, giving them an opportunity to raise awareness of the rewards of research participation as well as increasing visibility of the trial. We will produce clinical summary papers for clinician targeted journals.

Final dissemination events will be organised to report research finding to key stakeholders (e.g.- patients/national patient advocates, clinicians, NHS England-commissioners, GDP providers participating practices/participants) to deliver impact across wide audience. The Universities participating in the study will work with their local Press departments to assist with access to the media. Live streaming and on-demand post event viewing will be made available.

Intention to publish date
28/02/2025

Individual participant data (IPD) sharing plan
The datasets generated during and analysed during the current study will be available upon request from the Chief Investigator Jan Clarkson (j.e.clarkson@dundee.ac.uk). The datasets will be made available at the time the main results of the trial are published. The Chief Investigator, will, in collaboration with the sponsor, assess whether requests for data should be fulfilled. Consent is obtained from participants that information collected about them can be shared anonymously with other researchers to support future research.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		09/07/2021	12/07/2021	Yes	No
Other publications	Dentists' perspectives	09/03/2025	10/03/2025	Yes	No