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Can silver diamine fluoride (SDF) reduce the impact on young children of waiting for dental care?

Submission date
11/03/2025

Recruitment status
No longer recruiting

Registration date
13/03/2025

Overall study status
Completed

Last Edited
04/11/2025

Condition category
Oral Health

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

Plain English summary of protocol

Background and study aims
Dental extractions under general anaesthesia (DGA) are the most common reason for NHS hospital admission for children aged 6-10 years. Due to long waiting times for DGA, many children experience pain, infection, missed school, and sleepless nights. Silver diamine fluoride (SDF) is a treatment that can stop tooth decay in children's primary teeth. This study aims to see if using SDF can help children on DGA waiting lists by reducing pain and infection.

Who can participate?
Children aged 1-8 years who are on a DGA waiting list for dental extractions due to decayed primary teeth, along with their parents, can participate in the study.

What does the study involve?
Children will have SDF applied to their decayed primary teeth while they wait for DGA. Data will be collected on how many children accept the SDF treatment and their experiences. Parents and children will complete questionnaires about pain, infection, and oral health-related quality of life. Interviews will also be conducted to gather more detailed experiences.

What are the possible benefits and risks of participating?
The possible benefits include reduced pain and infection while waiting for DGA. Risks may include potential side effects of SDF treatment, although it is generally considered safe.

Where is the study run from?
Sheffield Teaching Hospitals NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
March 2025 to September 2025

Who is funding the study?
Royal College of Surgeons of England (UK)

Who is the main contact?
Dr Laura Timms, l.timms@sheffield.ac.uk

Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
351045

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
CPMS 65395

Study information

Scientific Title
Can silver diamine fluoride reduce negative impacts for young children with dental caries awaiting treatment under general anaesthesia: a feasibility study

Study objectives
This feasibility study aims to investigate uncertainties around recruitment, retention and methodology that would inform a larger definitive trial to establish whether SDF reduces negative impacts for young children with dental caries while awaiting DGA.

Ethics approval required

Ethics approval required

Ethics approval(s)
approved 03/03/2025, West Midlands - Edgbaston Research Ethics Committee (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 2071048137; edgbaston.rec@hra.nhs.uk), ref: 25/WM/0014

Study design
Interventional non-randomized

Primary study design
Interventional

Study type(s)
Treatment

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

Interventions
Baseline information will be collected including: age, sex, ethnicity, postcode in order to determine deprivation decile, and free school meal status as a proxy for social deprivation. The number of carious teeth will be recorded, as will the number of carious teeth planned for treatment under dental general anaesthesia should different (for example, some may receive restorative treatment ahead of GA), and the number of teeth suitable for SDF application. Any medical comorbidities and medications will be recorded. Oral hygiene practice will be recorded.

The application of SDF will then be completed at either this visit or a later visit, depending on participant preference and clinical time available. The proportion of children recruited who ultimately accept the SDF treatment successfully will be recorded. Feedback will be recorded about patient, parent, and dental team experiences of SDF application. A 2-item questionnaire will be given to parents and children to ask about the acceptability/treatment experience of the SDF application. If a subsequent appointment is arranged, at the participant preference, and further SDF applied, this information will be collected again.

Every month while on the waiting list, short parental questionnaires via post/text/online /telephone (according to participant preference) will ascertain whether the child has suffered from pain or infection whilst on the waiting list. PPI advice felt this was enough time to still remember an experience of pain or infection, but not too frequent as to be a burden. This will be a 5-item questionnaire. This will be collected by LT remotely via post/text/online/telephone (according to participant preference).

Within four weeks of the DGA visit, parents and children will be asked to complete an oral health-related quality of life questionnaire. This will be the PCPQ-16 for parents and CARIES-QC for children. This will either be collected in person on the date of GA, or remotely via email, post, text, or phone call at the parents' preference close to the time of GA (within 4 weeks).

On the date of DGA, there will be an assessment of the presence of infection on GA date to allow assessment of whether this is a suitable outcome measure, and whether it is feasible to measure on the date of GA. This will be either recorded by the local research team on the day of the DGA, or by reviewing the dental records and completing this retrospectively.

At a point during the study, interviews will be undertaken via telephone/virtual platform with children and parents depending on participant preference by LT the CI. These will last around half an hour and discuss their experiences of being part of the study, and how the study processes could be improved for a full trial. The interviews will be undertaken with children and parents present. It is anticipated due to their young age some interviews with children will lack depth, and some parents may wish to do the interview alone if they do not feel it is appropriate for their child.

Simple descriptive statistics will be undertaken for quantitative data to include rates of acceptability, recruitment, and retention. An assessment will be made of the data quality provided in order to review whether outcome measures are feasible and provide quality data. Framework analysis will be carried out for interview data. The framework will be inductive and data-driven. This will be led by LT, with review and input on the analysis from ZM, PD, HDR, and NI.

Intervention Type
Supplement

Primary outcome(s)
1. Numbers of potential participants approached, declined, accepted, recruited is measured using a screening log and recruitment log at baseline
2. Reasons for child/parent dyads declining participation is measured using a screening log at baseline
3. Proportion of child/parent dyads recruited who accept the SDF treatment successfully is measured using a case report form (CRF) at baseline and follow-up visits
4. Feedback about patient, parent, and dental team experiences of SDF application is measured using a 2-item questionnaire at baseline and follow-up visits
5. Numbers of participants retained up to DGA is measured using a CRF and withdrawal log at baseline and follow-up visits
6. Reasons for child/parent dyads withdrawing participation is measured using a CRF and withdrawal log at baseline and follow-up visits
7. Oral health-related quality of life (OHRQoL) is measured using Caries-QC and P-CPQ questionnaires at baseline and within 4 weeks of DGA visit
8. Pain or infection while on the waiting list is measured using a 5-item parental questionnaire via post/text/online/telephone every month while on the waiting list
9. Presence of infection on GA date is measured using a CRF by the local research team on the day of DGA or by reviewing dental records retrospectively
10. Teeth with clinically arrested caries is measured using a CRF at follow-up visits

Key secondary outcome(s))
There are no secondary outcome measures

Completion date
30/09/2025

Eligibility

Key inclusion criteria
1. Children, aged 1-8 years with caries in their primary dentition
2. They will have been placed on DGA waiting lists for ‘non-urgent’ (anticipated wait time over 1

month) dental extractions/treatment of carious primary teeth at one of the participating sites
3. Parents will also be included as participants and these pairings will be termed child/parent dyads

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Child

Lower age limit
1 years

Upper age limit
8 years

Sex
All

Total final enrolment
31

Key exclusion criteria
1. Children with medical conditions which preclude SDF treatment

Date of first enrolment
01/05/2025

Date of final enrolment
31/10/2025

Locations

Countries of recruitment
United Kingdom

England

Wales

Study participating centre
Bradford District Care NHS Foundation Trust
New Mill
Victoria Road
Saltaire
Shipley

United Kingdom
BD18 3LD

Study participating centre
Sheffield Teaching Hospitals NHS Foundation Trust
Northern General Hospital
Herries Road
Sheffield
United Kingdom
S5 7AU

Study participating centre
Cardiff & Vale University Lhb
Woodland House
Maes-y-coed Road
Cardiff
United Kingdom
CF14 4HH

Sponsor information

Organisation
Sheffield Teaching Hospitals NHS Foundation Trust

ROR
https://ror.org/018hjpz25

Funder(s)

Funder type
Research council

Funder Name
Royal College of Surgeons of England

Alternative Name(s)
RCS England, RCS ENG, The Royal College of Surgeons of England, RCS

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available due to not having consent to share the data from participants.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes