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SMART filling for caries in primary teeth

Submission date 16/07/2018	**Recruitment status** Stopped	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data [_] Record updated in last year
Registration date 26/07/2018	**Overall study status** Stopped	
Last Edited 21/01/2026	**Condition category** Oral Health	

Plain English summary of protocol

Background and study aims
Tooth decay affects 60 -90% of children worldwide. Treatment usually involves drilling to remove bacteria and underlying softened tooth before placement of a filling. For children, amalgam fillings are banned from next year in the EU due to global mercury toxicity concerns. Furthermore, in the UK, alternative white composite fillings are rarely applied in local dental practice due to the lengthy and complex placement procedures. Instead hospital admittance is required to enable general anaesthesia. Resultant treatment delays can lead to significant pain, larger holes with a poorer chance of successful repair and ultimately no option except complete tooth removal. A solution developed over the past decade is a new SMART composite that can be placed directly onto the child's softened tooth structure without drilling, anaesthetic or current complex bonding procedures. The aim of the study is to assess restoration failure following 6 months placement of the SMART composite on minimally prepared cavities in children's teeth.

Who can participate?
Children aged 6 to 12 with decayed primary teeth that require extraction (stage 1) or children aged 5 to 9 restoration (stage 2)

What does the study involve?
Children taking part in stage 1 have primary teeth decayed beyond repair that require extraction. The new filling material is placed in the affected tooth for the typical 4-week period between hospital appointments for consent and tooth extraction. Participants are followed up to confirm that the material remains in place to reduce pain and disease progression without any unforeseen side effects. In stage 2, children have their decayed primary molar teeth restored with the new composite. Restoration success is assessed at standard 12-month check-ups.

What are the possible benefits and risks of participating?
Children are set to benefit most if successful as at present thousands of children every year have general anaesthetics for dental treatment. Simplifying the procedure for filling decayed teeth and reducing failure rates will help decrease this number. This composite can be placed directly onto the child's softened tooth without drilling, anaesthetic or current complex bonding procedures reducing time spent in the dental chair. This composite eliminates the need to place a mercury-containing restoration. The study will determine whether there are any side effects or reactions and prove the unique selling properties of the new material. While this specific

composite is untested clinically, the main individual components are commonly used in dental composites that have been in clinical use for over 60 years. The two additional new components are added at low levels and used extensively at much higher levels in bone cements (MCPM) or as a preservative in food (polylysine). The filling material will only be placed in primary teeth which will ultimately fall out. The study has been designed to ensure all participants are exposed to minimum risk whilst confirming the safety and feasibility of the composite material.

Where is the study run from?
UCL Eastman Dental Institute (UK)

When is the study starting and how long is it expected to run for?
March 2018 to January 2026

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

Who is the main contact?
Dr Paul Ashley, p.ashley@ucl.ac.uk

Contact information

Type(s)
Scientific

Contact name
Dr Paul Ashley

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Additional identifiers

Integrated Research Application System (IRAS)
253369

Protocol serial number
CPMS 38878, IRAS 253369

Study information

Scientific Title
SMART composite (Self-bonding Material for Atraumatic Restorative Treatment) restoration of children’s primary molar teeth after minimal caries removal: Class IIa device in a single site, single arm study

Acronym
SMART

Study objectives
To ensure that the filling material does not compromise the clinical condition or safety of patients and users; that it achieves its intended purposes; that any risks associated are acceptable when weighed against the benefits to the patient and compatible with a high level of protection of health and safety.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Approved 30/07/2018 Stage 1, London - Bloomsbury Research Ethics Committee (HRA RES Centre Manchester, 3rd Floor Barlow House, 4 Minshull Street, Manchester, M1 3DZ, UK; telephone unavailable; bloomsbury.rec@hra.nhs.uk), ref: 18/EE/0191
2. Approved 04/03/2022 Stage 2, London - Bloomsbury Research Ethics Committee (HRA RES Centre Manchester, 3rd Floor Barlow House, 4 Minshull Street, Manchester, M1 3DZ, UK; telephone unavailable; bloomsbury.rec@hra.nhs.uk), ref: 22/LO/0089

Study design
Non-randomized interventional study

Primary study design
Interventional

Study type(s)
Treatment

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

Interventions
Current interventions as of 26/08/2021:
Stage 1
Potential participants will already be under treatment at the Eastman Dental Hospital for management of dental decay. These children will have decayed primary molar teeth that require extraction and will be aged between 6 and 12 years. During this appointment, parents/guardians and potential participants will have the study explained by a clinician, information pack will be given to both and they will be invited to take part.
At the next visit after being invited to take part, children will be consented for entry into the study. Children who consent will have the new filling material placed in the tooth due for extraction. Additionally, patients will receive a telephone consultation following placement of the filling to ensure no adverse events or reactions had occurred. Parents/guardians and participants will also be supplied with contact information that will allow adverse events or reactions to be reported at any stage of the trial. Patients and carers will be asked to assess how easy or difficult placement of the new filling was. After 4 weeks participants will return for extraction of the tooth. They will be asked again about any adverse or unexpected events or reactions. Following extraction, participants will have no further involvement.

Stage 2
Potential participants will already be under treatment at the Eastman Dental Hospital for management of dental decay. These children will have decayed primary molar teeth that require a filling and will be aged between 5 and 9 years. During this appointment, parents/guardians and potential participants will have the study explained by a clinician, information pack will be given to both and they will be invited to take part.
At the next visit after being invited to take part children will be consented for entry into the study. Children who consent will have the place the new filling material placed in one tooth. Patients and carers will be asked to assess how easy or difficult placement of the new filling. After three months participants will be contacted by phone and asked about any adverse or unexpected events or reactions. After 12 months the fillings will be assessed to see if they are still in place. The children will be checked again for any unexpected or adverse events or reactions. Children who do not consent will have an ordinary filling placed in the normal way.

Previous interventions:
Stage 1
Potential participants will already be under treatment at the Eastman Dental Hospital for management of dental decay. These children will have decayed primary molar teeth that require extraction and will be aged between 6 and 12 years. During this appointment, parents/guardians and potential participants will have the study explained by a clinician, information pack will be given to both and they will be invited to take part.
At the next visit after being invited to take part, children will be consented for entry into the study. Children who consent will have the new filling material placed in the tooth due for extraction. Additionally, patients will receive a telephone consultation following placement of the filling to ensure no adverse events or reactions had occurred. Parents/guardians and participants will also be supplied with contact information that will allow adverse events or reactions to be reported at any stage of the trial. Patients and carers will be asked to assess how easy or difficult placement of the new filling was. After 4 weeks participants will return for extraction of the tooth. They will be asked again about any adverse or unexpected events or reactions. Following extraction, participants will have no further involvement.

Stage 2
Potential participants will already be under treatment at the Eastman Dental Hospital for management of dental decay. These children will have decayed primary molar teeth that require a filling and will be aged between 6 and 12 years. During this appointment, parents/guardians and potential participants will have the study explained by a clinician, information pack will be given to both and they will be invited to take part.
At the next visit after being invited to take part children will be consented for entry into the study. Children who consent will have the place the new filling material placed in one tooth. Patients and carers will be asked to assess how easy or difficult placement of the new filling. After three months participants will be contacted by phone and asked about any adverse or unexpected events or reactions. After six months the fillings will be assessed to see if they are still in place. The children will be checked again for any unexpected or adverse events or reactions. Children who do not consent will have an ordinary filling placed in the normal way.

Intervention Type
Device

Phase
Phase II

Drug/device/biological/vaccine name(s)
Renewal MI

Primary outcome(s)
Current primary outcome measure as of 26/08/2021:
1. Safety will be assessed through examination at month 1 in the stage 1 of the study. In stage 2 it will be assessed by a phone conversation in at 3 months in stage 2 and at the end by examination (12 months)
2. Restoration failure assessed through examination at 12 months

Previous primary outcome measure:
1. Safety will be assessed through examination at month 1 in the stage 1 of the study. In stage 2 it will be assessed by a phone conversation in at 3 months in stage 2 and at the end by examination (6 months)
2. Restoration failure assessed through examination at 6 months

Key secondary outcome(s))
Current secondary outcome measures as of 26/08/2021:
Acceptability will be measured using a simple questionnaire at the end of stage 2 (12 months)

Previous secondary outcome measures:
Acceptability will be measured using a simple questionnaire at the end of stage 2 (6 months)

Completion date
01/01/2026

Reason abandoned (if study stopped)
Lack of staff/facilities/resources

Eligibility

Key inclusion criteria
Current participant inclusion criteria as of 26/08/2021:
Stage 1:
1. Children 6 to 12 years of age
2. One primary molar with a carious cavity affecting one or more surfaces (International Caries Detection and Assessment System (ICDAS) score 4,5) that requires temporary dressing whilst awaiting extraction
3. Subject willing to sit in the dental chair and cooperate with clinicians on planned protocol treatment

Stage 2:
1. Children 5 to 9 years of age
2. One primary molar with a two surface carious cavity (occlusal and proximal surface) ICDAS score 4,5 that requires restoration
3. Subject willing to sit in the dental chair and cooperate with clinicians on planned protocol treatment

Previous participant inclusion criteria:
Stage 1:
1. Children 6 to 12 years of age

2. One primary molar with a carious cavity affecting one or more surfaces (International Caries Detection and Assessment System (ICDAS) score 4,5) that requires temporary dressing whilst awaiting extraction
3. Subject willing to sit in the dental chair and cooperate with clinicians on planned protocol treatment

Stage 2:
1. Children 6 to 12 years of age
2. One primary molar with a two surface carious cavity (occlusal and proximal surface) ICDAS score 4,5 that requires restoration
3. Subject willing to sit in the dental chair and cooperate with clinicians on planned protocol treatment

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Child

Lower age limit
5 years

Upper age limit
12 years

Sex
All

Total final enrolment
0

Key exclusion criteria
Stage 1:
1. Unable to give assent/consent
2. Non-carious anomaly of structure such as amelogenesis imperfecta
3. Patients with significant pain and/or infection who require an urgent management (assessed by standard clinical investigations)
4. Teeth with non-vital exposed pulps with draining pus (as per standard care)
5. Methacrylate allergy

Stage 2:
1. Unable to give assent/consent
2. Non-carious anomaly of structure such as amelogenesis imperfecta
3. Subject NOT willing to sit in the dental chair and cooperate with clinicians on planned protocol treatment
4. Methacrylate allergy

Date of first enrolment

01/11/2022

Date of final enrolment
01/01/2026

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
UCL Eastman Dental Institute
47-49 Huntley St
London
England
WC1E 6DG

Sponsor information

Organisation
University College London

ROR
https://ror.org/02jx3x895

Funder(s)

Funder type
Government

Funder Name
NIHR Central Commissioning Facility (CCF); Grant Codes: II-LB-0214-20002

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication.

IPD sharing plan summary

Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No
HRA research summary			28/06/2023	No	No
Other unpublished results	Sponsor stage 1 summary report	20/10/2021	20/10/2021	No	No
Protocol file		25/07/2018	02/04/2019	No	No