ISRCTN17029222 https://doi.org/10.1186/ISRCTN17029222

Seal or Varnish? A comparison of the cost and effectiveness of sealants and varnish in preventing dental decay

Submission date 18/10/2010	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 21/10/2010	**Overall study status** Completed	
Last Edited 24/07/2019	**Condition category** Oral Health	

Plain English summary of protocol

Background and study aims
Tooth decay (caries) can be prevented by applying pit and fissure sealants to the biting surface of the tooth. This treatment consists of a plastic coating that covers the rough biting surface which harbours decay-causing bacteria. Applying fluoride varnish every six months can also prevent tooth decay. This works by strengthening the tooth enamel, making it more resistant to decay. What is not known is which of these two modes of treatment works best and which is the most cost-effective. It is also not know which of these treatments is the most acceptable from the perspective of children and their parents. Applying fissure sealant requires a complicated dental intervention, while varnish application simply involves painting the tooth surface. This study will examine the relative clinical and cost effectiveness of these treatments and investigate their acceptability to children and their parents.

Who can participate?
Year 2 children (aged 6 - 7) attending the schools participating in the current Cardiff and Vale University Health Board Fissure Sealant Programme

What does the study involve?
Participants are randomly allocated to receive either fissure sealants on their first permanent molars or fluoride varnish. The number of children in each group who have tooth decay in their first molar teeth are compared after three years, along with the cost effectiveness and patient acceptability of the treatments.

What are the possible benefits and risks of participating?
Not provided at time of registration

Where is the study run from?
Cardiff University Dental School (UK)

When is the study starting and how long is it expected to run for?
June 2011 to December 2014

Who is funding the study?
NIHR Health Technology Assessment Programme - HTA (UK)

Who is the main contact?
Prof. Ivor Chestnutt

Contact information

Type(s)
Scientific

Contact name
Prof Ivor Chestnutt

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Additional identifiers

Clinical Trials Information System (CTIS)
2010-023476-23

Protocol serial number
HTA 08/104/04; SPON766-09

Study information

Scientific Title
A randomised trial to determine the relative cost and effectiveness of pit and fissure sealants and fluoride varnish in preventing dental decay

Acronym
Seal or Varnish?

Study objectives
Pit and fissure sealants (PFS) and fluoride varnish (FV) are established technologies for the prevention of dental caries. However to date there is insufficient evidence to determine if there is a difference between the effectiveness of PFS and FV. Importantly from the perspective of the NHS, there is insufficient evidence on which to make recommendations for clinical practice and which (PFS or FV) represents the most cost effective technology.

The proposed clinical trial will address the following question: "What is the relative cost and effectiveness of pit and fissure sealants and fluoride varnish in preventing dental decay in the first permanent molar teeth of children?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Pending at time of registration

Study design
Prospective two-arm randomised controlled trial

Primary study design
Interventional

Study type(s)
Treatment

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

Interventions
Participants will be randomly allocated to receive either of the following investigational medicinal products (IMPs). Participants will be treated within two weeks of being randomised.

1. Pit and Fissure Sealant (PFS):
Eligible study participants randomised to receive PFS will have PFS on all erupted and sound first permanent molars (FPM) at baseline. These will be applied by a dental hygienist according to conventional clinical protocol. These participants will be re-examined by the hygienist at six-monthly intervals and sealant retention checked and reapplied/topped up if deficient.

2. Fluoride Varnish (FV):
Eligible study participants randomised to receive FV (22,600 ppm F) will have FV applied to all partially erupted, erupted and sound FPMs at baseline. These will be applied by a dental hygienist according to a conventional clinical protocol. These participants will be re-examined by the hygienist at six-monthly intervals and FV reapplied to all FPMs.

The proposed duration for both PFS and FV treatment is three years. The proposed frequency and duration of follow up is 3 years post-baseline assessment. Sealant check and varnish application will take place at six-monthly intervals and clinical examinations (recording of caries status) will take place yearly (month 12, 24 and 36) post-treatment.

Intervention Type
Procedure/Surgery

Primary outcome(s)
1. Development of dental caries on the occlusal surface of first permanent molars at 36 months
2. Cost-effectiveness outcome measure: costs will be determined for the health service following discussions with key relevant dental and finance staff where time taken for treatments, clinic and staff involvement, materials and equipment used will be logged and costed (using published unit costs) to determine costs of treatment for each technology. The costs for children and their families will be determined by an analysis of questionnaires completed during the treatment phase. The costs to participating schools will be derived via questions in the semi-structured interviews conducted with staff from participating schools. In

terms of outcomes the indicators of effect for clinical effectiveness will be used along with costs to estimate the relative cost-effectiveness of the two approaches. In addition, utility values will be measured as Quality Adjusted Tooth Years (QATYs), which is the production of additional years of life (tooth-year) of each tooth adjusted for the quality of the tooth. An unrestored tooth has a QATY equal to 1 in the year that it was restoration-free, while a restored, crowned, or root canal treated tooth has a QATY less than perfect (i.e., less than 1) in the year that it was restored and subsequent years. The QATY for an extracted tooth is equal to 0 in that year and subsequent years.
3. Health related quality of life scores will be calculated at entry, 12 months, 24 months and 36 months. These scores will be mapped onto utility scores to generate QALYs.

Key secondary outcome(s))
1. Patient acceptability, measured using a modified version of the Delighted-Terrible Faces Scale. This will be triangulated via a series of semi-structured interviews with parents/school staff/clinical personnel on treatment acceptability
2. During the clinical placement of the technologies under investigation, we will record the following indicators of patient acceptability/adverse outcomes:
2.1. Vomiting
2.2. Crying
2.3. Gagging
2.4. Excessive arm/leg movements
2.5. Other signs of distress

Completion date
21/12/2015

Eligibility

Key inclusion criteria
1. Year 2 children (aged 6 - 7 years) attending the schools participating in the current Cardiff and Vale University Health Board Fissure Sealant Programme
2. Children with at least one-fully erupted caries-free first permanent molar

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Child

Lower age limit
6 years

Upper age limit
7 years

Sex
All

Key exclusion criteria
Applied at screening:
1. Children whose parents refuse consent
2. Children who at the time of the clinical examination or PFS/FV placement refuse assent
3. Children whose medical history precludes inclusion (i.e., those with a history of hospitalisation for asthma, or severe allergies, or allergy to Elastoplast)
4. Children with ulcerative gingivitis or stomatitis
5. Children with any facial or oral infections, e.g., cold sores
6. Children with known sensitivity to colophony (kolophonium), or any of the product ingredients (e.g. methylacrylate in PFS)
7. children with any abnormality of the lips, face or soft tissues of the mouth considered by the investigator to preclude acceptable application of either PFS or FV
8. Children who are showing obvious signs of systemic illness (e.g. colds, 'flu, chicken pox, etc.,) should also be excluded on that day

Applied at baseline examination:
9. Children without at least one fully-erupted caries-free first permanent molar

Date of first enrolment
01/06/2011

Date of final enrolment
31/12/2014

Locations

Countries of recruitment
United Kingdom

Wales

Study participating centre
Cardiff University Dental School
Cardiff
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CF14 4XY

Sponsor information

Organisation
Cardiff University (UK)

ROR
https://ror.org/03kk7td41

Funder(s)

Funder type
Government

Funder Name
Health Technology Assessment Programme

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

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/04/2017		Yes	No
Results article	results	01/07/2017		Yes	No
Protocol article	protocol	20/11/2012		Yes	No