NIHR Health Technology Assessment programme funded project

South East Wales Trials Unit
Uned Ymchwil De-ddwyrain Cymru

CARDIFF UNIVERSITY
PRIFYSGOL CAERDYDD

SEAL OR VARNISH

PROTOCOL SYNOPSIS

Study Title	Seal or Varnish? A Randomised Trial To Determine The Relative Cost And Effectiveness Of Pit And Fissure Sealants And Fluoride Varnish In Preventing Dental Decay
Sponsor ref.	SPON766-09
EudraCT Nº	2010-023476-23
Clinical Phase	IV
Trial Design	Randomised, assessor-blinded, two-arm, parallel group trial in 6-7 year old schoolchildren. Clinical procedures and assessments will be performed at primary schools in South Wales via the use of a mobile dental clinic.
Trial Participants	Male and female 6-7 year old schoolchildren attending 'Community First' Schools (as designated by Welsh Assembly Government) in South Wales, UK
Planned Sample Size	920 (460 per arm)
Number of sites	1 mobile dental clinic covering approximately 50 schools
Follow-up duration	3 years from first IMP administration
Planned Trial Period	3.5 years (from first patient consent to last assessment)
Objectives	*Primary:* To compare the clinical effectiveness of Pit and Fissure Sealants (PFS) and Fluoride Varnish (FV) in preventing dental caries in first permanent molars in 6-7 year-olds, as determined by: • The proportion of children developing caries on any one of up to four treated first permanent molars • The number of treated first permanent molar teeth caries-free at 36 months *Secondary:* • To establish the costs and budget impact of PFS and FV delivered in a community/school setting and the relative cost-effectiveness of these technologies • To examine the impact of PFS and FV on children and their parents/carers in terms of quality of life/treatment acceptability measures. • To examine the implementation of treatment in a community setting with respect to the experience of children, parents, schools and clinicians.

Outcome Measures	*Primary:* The primary outcome measure will be the development of dental caries in first permanent molars at 36 months *Secondary:* Cost-effectiveness outcome measures Costs to the NHS for each technology will be determined at baseline, 12 months, 24 months and 36 months in conjunction with relevant dental and finance staff and will account for time taken for treatments, clinic and staff involvement, materials and equipment (to be logged and costed using published unit costs). The costs for children and their families will be determined from questionnaires completed during the treatment phase. The costs to participating schools will be derived via semi-structured interviews conducted with staff from participating schools. Potential costs of treatments avoided will also be determined. The relative cost-effectiveness will be estimated by integrating the clinical and cost effectiveness. In addition, utility values will be measured as Quality Adjusted Tooth Years (QATYs). Health related quality of life (QoL) scores will be determined at 12 months, 24 months and 36 months using the Child Health Utility 9D (CHU-9D) questionnaire. These scores will be mapped onto utility scores to generate Quality Adjusted Life Years (QALYs). Treatment Acceptability outcome measures A modified version of the Delighted-Terrible Faces Scale will be used to determine patient acceptability. This will be triangulated via a series of semi-structured interviews with children, parents, school staff and clinical personnel on treatment acceptability. Acceptability of the clinical placement of the technologies under investigation from the perspective of dental staff will be assessed using observational scales, and the following indicators of patient acceptability/adverse outcomes will be recorded: vomiting, crying, gagging, excessive arm/leg movements and other signs of distress. A sample of non-participating parents and parents who withdraw their children from the trial will be invited to partake in an interview to determine reasons for non-participation/withdrawal.
Investigational Medicinal Products	• Pit and Fissure Sealant: Delton® Light Curing Pit & Fissure Sealant (Dentsply Ltd; CE0086), supplied as 2.7 ml bottles for multiple applications. Applied topically as a thin layer to occlusal surface of eligible teeth at 0 months and re-applied (only if required) at 6, 12, 18, 24, and 30 months. • Fluoride Varnish: Duraphat® 50 mg/ml dental suspension, (Colgate-Palmolive (UK) Ltd; PL 00049/0042), supplied as 10 ml tubes for multiple applications. Applied topically as a thin layer to occlusal surface of eligible teeth at 0, 6, 12, 18, 24, and 30 months. As per SmPC, dosage per single application will not exceed 0.4 ml.

Assessment schedule

Data Type	Prior to Baseline Evaluation	Baseline Evaluation	Randomisation & Initial PFS/ FV Application	Follow Up Period (months)					
				6	12	18	24	30	36
Clinical Data									
Medical/Dental History/Demographics	X				X		X		
Eligibility (Inclusion/Exclusion Criteria)		X	X						
Caries Risk Related Habits			X		X		X		X
ICDAS caries assessment		X			X		X		X
Pre-treatment assessment[1]			X	X	X	X	X	X	
Adverse Event assessment			X	X	X	X	X	X	X
Health Economics Data									
NHS resource usage interviews			X		X		X		X
Parental Resource Questionnaire			X		X		X		X
School Resource Questionnaire			X		X		X		X
Health-related Quality of Life (CHU9D)					X		X		X
Treatment Acceptability & Process Evaluation Data									
Observational Scale [2]			X	X	X	X	X	X	
Delighted-Terrible Faces Scale			X	X	X	X	X	X	
Interviews with children			X						X
Interviews with parents			X						X
Questionnaires/Interviews with schools[3]			X						X
Interviews with Dental Team[4]			X		X		X		X
Interviews with non-consenting parents	**I< ---------- >I**								
Interviews with non-responding parent	**I< ---------- >I**								
Interviews with withdrawing parents			**I< ---------- as required ---------- >I**						

[1] Assessment limited to condition of previously-applied sealant and/or pre-application risk assessment for sealant/varnish
[2] Completed by both Dental Hygienist **and** Dental Nurse during/immediately after treatment
[3] All schools will be asked to complete a questionnaire at the beginning of the study with a sample of schools invited for telephone interview at the end of the study
[4] Dental Team composed of Dental Officer, Dental Hygienist and Dental Nurse