ISRCTN72589426 https://doi.org/10.1186/ISRCTN72589426

To measure the benefit of fluoride varnish in preventing dental decay when applied to permanent teeth of children for 3 years in the school setting

Submission date
05/05/2011

Recruitment status
No longer recruiting

Registration date
17/06/2011

Overall study status
Completed

Last Edited
29/10/2015

Condition category
Oral Health

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Tooth decay is a growing problem in children. The amount of children suffering from cavities (where an area of the tooth decays causing a hole) and requiring dental treatment (fillings) has risen dramatically in recent years. Many children have high amounts of sugar in their diets. The bacteria which are naturally present in the mouth use these sugars to produce acids, which damage the protective enamel on teeth over time, causing cavities. Cavities are most common in molars (back teeth) as they can be more difficult to keep clean when brushing teeth. Fluoride is a natural mineral in the diet, which helps to strengthen tooth enamel, protecting against tooth decay. Research has shown that applying fluoride varnish to teeth can help to stop and prevent tooth decay which leads to the development of cavities. The aim of this study is to find out whether fluoride varnish can help to prevent tooth decay in children.

Who can participate?
Children aged 7-8 who attend state schools in Northwest England (UK)

What does the study involve?
The included schools are randomly allocated into two groups. Children who attend schools in the first group have a fluoride varnish applied to their first permanent molars (back teeth), up to nine times over a three year period. Children who attend schools in the second group do not receive any additional treatment, and continue with their normal tooth care routines. Over the course of the study, the amount of children who need to have fillings is recorded in both groups.

What are the possible benefits and risks of participating?
Participants who receive the fluoride varnish treatment may develop fewer cavities as their teeth have a greater amount of protection than brushing alone. There no notable risks of taking part in the study, although the application of the fluoride varnish may be an inconvenience to some children.

Where is the study run from?
95 Local Authority primary schools in Northwest England (UK)

When is the study starting and how long is it expected to run for?
February 2006 to April 2009

Who is funding the study?
Department of Health (UK)

Who is the main contact?
Professor Keith Milsom
keith.milsom@hsthpct.nhs.uk

Contact information

Type(s)
Scientific

Contact name
Prof Keith Milsom

Contact details
Victoria House
Holloway
Runcorn
Cheshire
Runcorn
United Kingdom
WA7 4TH
+44 (0)192 859 3733
keith.milsom@hsthpct.nhs.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
PHI/03/C1/017 UK Clinical Research Network portfolio number: 4292

Study information

Scientific Title
A cluster randomised controlled trial to measure the benefit of fluoride varnish preventing dental decay when applied to permanent teeth of children for 3 years in the school setting

Study objectives

There is a difference in dental decay experience in posterior permanent teeth of children aged 9-11 years at outcome who have received up to nine applications of fluoride varnish when compared with children receiving no fluoride varnish.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Cumbria & Lancashire REC B approved on 13th December 2005, ethics ref: 05/Q1309/2

Study design
Cluster randomised two compartment parallel trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Prevention

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

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

Interventions
The application of fluoride varnish on the occlusal surfaces of the first permanent molars up to nine times over a three year period.

The control group had no intervention.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Fluoride varnish

Primary outcome measure
The decayed, filled surfaces increment in first permanent molars on the intention-to-treat (ITT) population. The increment will be measured visually.

Secondary outcome measures
1. The decayed, filled surfaces increment in deciduous molars on the ITT population. The increment will be measured visually.
2. A sub group analysis for the frequency of applications of the varnish

Overall study start date
20/02/2006

Completion date
03/04/2009

Eligibility

Key inclusion criteria
1. Schools - all state maintained Local Authority primary schools in the study area. Participating schools must have formally agreed to take part int he study.
2. Children - Aged 7-8 years inclusive of children who attend Local Authority primary schools. Participants must have an informed consent form signed by a parent or legal guardian permitting participation of their child.

Participant type(s)
Patient

Age group
Child

Lower age limit
7 Years

Upper age limit
8 Years

Sex
Both

Target number of participants
80 schools, 2080 children

Key exclusion criteria
1. Presence of fixed orthodontic appliances involving more than four permanent teeth
2. Participation in any other clinical study during the three months preceding the initial examination
3. Subjects with a history of asthma that required hospitalisation
4. Subjects with a histroy of severe allergic reactions that required hospitalisation
5. Subjects experiencing ulcerative gingivitis or stomatitis
6. Subjects with a history of allergy to any of the ingredients in the test products
7. Subject is uncooperative/ unable to be examined
8. Children attending special schools

Date of first enrolment

20/02/2006

Date of final enrolment
03/04/2009

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Victoria House
Runcorn
United Kingdom
WA7 4TH

Sponsor information

Organisation
University of Manchester (UK)

Sponsor details
Oxford Road
Manchester
England
United Kingdom
M13 9PL
+44 161 275 6782
martin.tickle@manchester.ac.uk

Sponsor type
University/education

ROR
https://ror.org/027m9bs27

Funder(s)

Funder type
Government

Funder Name
Department of Health (UK) - National Co-ordinating Centre for Research Capacity Development, Public Health Initiative (PHI/03/C1/017)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/11/2011		Yes	No