

# 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

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<b>Registration date</b> 17/06/2011	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 29/10/2015	<b>Condition category</b> Oral Health	<input type="checkbox"/> 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

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## Contact information

### Type(s)

Scientific

### Contact name

Prof Keith Milsom

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## Additional identifiers

### Protocol serial number

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

**Study type(s)**

Prevention

**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(s)**

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

**Key secondary outcome(s)**

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

**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 in the 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

**Healthy volunteers allowed**

No

**Age group**

Child

**Lower age limit**

7 years

**Upper age limit**

8 years

**Sex**

All

**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 history 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**

United Kingdom

England

**Study participating centre**

Victoria House

Runcorn

United Kingdom  
WA7 4TH

## Sponsor information

### Organisation

University of Manchester (UK)

### 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

### 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?
<a href="#">Results article</a>	results	01/11/2011		Yes	No