

The Mancunian Fluoride Varnish Project

Submission date 12/09/2003	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 12/09/2003	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 17/07/2009	Condition category Oral Health	☐ Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
N0353062296

Study information

Scientific Title

Study objectives

Can fluoride varnish (Duraphat®) reduce dental caries among school children when used as a public health measure?

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Primary study design

Interventional

Study design

Randomised single blind controlled trial

Study type(s)

Prevention

Health condition(s) or problem(s) studied

Oral Health: Cariology

Interventions

Quantitative: Cluster randomised controlled trial in 20 sites with a single blindness. The children in 'test' received applications of fluoride varnish twice yearly, provided by dental therapists using mobile equipment in schools. The 'control' children received no fluoride varnish. All children were given paste and brushes at the time of baseline and 26 month examinations.

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

To measure the effects of fluoride varnish, applied twice yearly for 2 years, in schools, on the incidence of new carious lesions and control of existing lesions in the primary and permanent dentition.

Key secondary outcome(s)

Not provided at time of registration

Completion date

01/09/2004

Eligibility**Key inclusion criteria**

Year 2 and Year 3 children in schools in South Manchester.

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Child

Sex

All

Key exclusion criteria

Does not match inclusion criteria

Date of first enrolment

01/06/2000

Date of final enrolment

01/09/2004

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

Central Manchester Primary Care NHS Trust

Manchester

United Kingdom

M21 7RL

Sponsor information

Organisation

Department of Health (UK)

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Manchester Primary Care NHS Trust (UK)

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?
Results article	results	01/10/2007		Yes	No