

A randomised controlled trial to determine the effectiveness of glass ionomer sealants in pre-school children

Submission date 23/01/2004	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 23/01/2004	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 20/09/2010	Condition category Oral Health	<input type="checkbox"/> 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
RDO/90/12

Study information

Scientific Title

Study objectives

A randomised control trial to determine the effectiveness of glass ionomer sealants in pre-school children as a preventative measure designed to reduce the incidence of dental caries. The outcomes of this trial are:

1. Reduction of dental caries in pre-school children at high risk of disease by the use of glass ionomer sealants as a preventative measure.
2. Evidence of the cariostatic effect of glass ionomer sealants placed as fissure sealants in the primary dentition, a potentially cost effective technique.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Randomised controlled trial

Primary study design

Interventional

Study type(s)

Prevention

Health condition(s) or problem(s) studied

Dental caries

Interventions

Added 27/08/10:

All children (n = 508) received a standard package of dental health education. Children in the test group (n = 241) had their first primary molars sealed with glass ionomer. All the children were re-examined once at varying intervals between 12 and 30 months.

Intervention Type

Other

Phase

Not Applicable

Primary outcome(s)

1. Caries incidence
2. Acceptability of the techniques to parents and children
3. Cost effectiveness

Key secondary outcome(s)

Not provided at time of registration

Completion date

01/01/2003

Eligibility

Key inclusion criteria

Infants and children 18 to 66 months in areas with high levels of disease (decayed, missing and filled teeth [dmft] status is 2.5 at five years) in South Wales.

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Child

Lower age limit

16 months

Upper age limit

66 months

Sex

All

Key exclusion criteria

Children over 66 months.

Date of first enrolment

02/01/1999

Date of final enrolment

01/01/2003

Locations

Countries of recruitment

United Kingdom

Wales

Study participating centre

Division of Dental Health and Development

Cardiff

United Kingdom

CF4 4XY

Sponsor information

Organisation

Record Provided by the NHS R&D 'Time-Limited' National Programme Register - Department of Health (UK)

Funder(s)

Funder type

Government

Funder Name

NHS National Programme for Primary Dental Care (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	main results	01/01/2005		Yes	No
Results article	results on difficulties of patient recruitment	01/05/2005		Yes	No