# A randomised controlled trial to determine the effectiveness of glass ionomer sealants in preschool children

Recruitment status	Prospectively reg
No longer recruiting	[_] Protocol
Overall study status	[] Statistical analysi
Completed	[X] Results
<b>Condition category</b> Oral Health	[] Individual particip
	No longer recruiting Overall study status Completed Condition category

### Plain English summary of protocol

Not provided at time of registration

### **Contact information**

Type(s) Scientific

Contact name Dr Barbara Chadwick

### **Contact details**

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### Additional identifiers

EudraCT/CTIS number

**IRAS** number

ClinicalTrials.gov number

Secondary identifying numbers

gistered

is plan

ipant data

RDO/90/12

### Study information

Scientific Title

### Study objectives

A randomised control trial to determine the effectiveness of glass ionomer sealants in preschool 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

**Secondary study design** Randomised controlled trial

**Study setting(s)** Other

**Study type(s)** Prevention

Participant information sheet

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

### Interventions

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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.
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### Intervention Type

Other

### Phase

Not Applicable

#### Primary outcome measure

1. Caries incidence

- 2. Acceptability of the techniques to parents and children
- 3. Cost effectiveness

**Secondary outcome measures** Not provided at time of registration

Overall study start date 02/01/1999

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

**Age group** Child

**Lower age limit** 16 Months

**Upper age limit** 66 Months

Sex

Both

**Target number of participants** 508

**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)

#### **Sponsor details**

The Department of Health Richmond House 79 Whitehall London United Kingdom SW1A 2NL

#### Sponsor type

Government

Website http://www.doh.gov.uk

### Funder(s)

**Funder type** Government

**Funder Name** NHS National Programme for Primary Dental Care (UK)

### **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?
<u>Results article</u>	main results	01/01/2005	Yes	No
<u>Results article</u>	results on difficulties of patient recruitment	01/05/2005	Yes	No