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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	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 23/01/2004	**Overall study status** Completed	
Last Edited 20/09/2010	**Condition category** Oral Health	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

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
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 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?
Results article	main results	01/01/2005		Yes	No
Results article	results on difficulties of patient recruitment	01/05/2005		Yes	No