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The effect of the intra oral slow release fluoride device in remineralisation of enamel and dentine in situ.

Submission date	Recruitment status	[ ] Prospectively registered
30/09/2005	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
30/09/2005	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
24/05/2016	Oral Health	[ ] Record updated in last year

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
N0436146538

Study information

Scientific Title
The effect of the intra oral slow release fluoride device in remineralisation of enamel and dentine in situ.

Study objectives
To evaluate the remineralisation of enamel and dentine using the slow release fluoride glass device. The remineralisation will be evaluated using micro hardness and transverse microradiography

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
Oral Health

Interventions
Randomised controlled trial. Random allocation to various flow rates

Intervention Type
Device

Phase
Not Specified

Primary outcome measure

A future device to prevent caries

Secondary outcome measures
Not provided at time of registration

Overall study start date
28/04/2004

Completion date
01/12/2004

Eligibility

Key inclusion criteria
Population from Yorkshire region. Total Target Recruitment: 25.

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
25

Key exclusion criteria
1. Aged less than 18 years old
2. DMFS below 12
3. Less than 18 natural teeth
4. Salivary flow rate of less than 0,25ml/min
5. If plaque pH does not fall by a one unit after 5min or 10 min of sucrose rinse.

Date of first enrolment
28/04/2004

Date of final enrolment
01/12/2004

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Department of Child Dental Health
Leeds
United Kingdom
LS2 9LU

Sponsor information

Organisation
Department of Health

Sponsor details
Richmond House
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Sponsor type
Government

Website
http://www.dh.gov.uk/Home/fs/en

Funder(s)

Funder type
Government

Funder Name
Leeds Teaching Hospitals NHS Trust (UK)

Funder Name
NHS R&D Support Funding

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