

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

Submission date 30/09/2005	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 30/09/2005	Overall study status Completed	☐ Statistical analysis plan ☐ Results
Last Edited 24/05/2016	Condition category Oral Health	☐ Individual participant data ☐ 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

Protocol serial number

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

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Prevention

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(s)

A future device to prevent caries

Key secondary outcome(s)

Not provided at time of registration

Completion date

01/12/2004

Eligibility**Key inclusion criteria**

Population from Yorkshire region. Total Target Recruitment: 25.

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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**

United Kingdom

England

Study participating centre

Department of Child Dental Health

Leeds

United Kingdom

LS2 9LU

Sponsor information**Organisation**

Department of Health

Funder(s)

Funder type

Government

Funder Name

Leeds Teaching Hospitals NHS Trust (UK)

Funder Name

NHS R&D Support Funding

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration