

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

<b>Submission date</b> 30/09/2005	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 30/09/2005	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 24/05/2016	<b>Condition category</b> Oral Health	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

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### Contact details

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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

**Study design**

Randomised controlled trial

**Primary study design**

Interventional

**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