

# 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

Mrs G Kotru

### Contact details

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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  
79 Whitehall  
London  
United Kingdom  
SW1A 2NL  
+44 (0)20 7307 2622  
dhmail@doh.gsi.org.uk

**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