# Effect of fluoride sustained slow release devices on fluoride, phosphate and calcium levels in plaque biofilms

Submission date	Recruitment status No longer recruiting	Prospectively registered	
29/09/2006		☐ Protocol	
Registration date	Overall study status	Statistical analysis plan	
29/09/2006	Completed	[X] Results	
Last Edited	Condition category	[] Individual participant data	
29/03/2012	Oral Health		

## 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 N0436165571

# Study information

Scientific Title

#### **Study objectives**

Determine the effect of the FSSRD on fluoride, calcium and phosphorus levels in undisturbed plaque biofilms in vivo for both adults and children.

#### 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)

**Not Specified** 

#### Health condition(s) or problem(s) studied

Oral Health

#### **Interventions**

Not provided at time of registration

#### Intervention Type

Device

#### Phase

**Not Specified** 

#### Primary outcome(s)

Increase concentration of Fluoride in dental plaque and saliva. Fluoride has anticariogenic effect. The device will help protect the teeth specially of high caries susceptible groups (medically compromised, patients with special needs etc).

## Key secondary outcome(s))

Not provided at time of registration

## Completion date

30/12/2008

# Eligibility

#### Key inclusion criteria

Population from Yorkshire

## Participant type(s)

#### **Patient**

## Healthy volunteers allowed

No

## Age group

**Not Specified** 

#### Sex

**Not Specified** 

#### Key exclusion criteria

Not provided at time of registration

#### Date of first enrolment

01/02/2005

#### Date of final enrolment

30/12/2008

## Locations

### Countries of recruitment

**United Kingdom** 

England

# Study participating centre Paediatric Department

Leeds United Kingdom LS2 9LU

# Sponsor information

## Organisation

Record Provided by the NHSTCT Register - 2006 Update - 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

## **Study outputs**

Output type	Details	Date created Date added	Peer reviewed?	Patient-facing?
Results article	results	01/06/2011	Yes	No
Participant information sheet	Participant information sheet	11/11/2025 11/11/2025	No	Yes