

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

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

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
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

Primary study design

Interventional

Study design

Randomised controlled trial

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