ISRCTN37527364 https://doi.org/10.1186/ISRCTN37527364

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 [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 29/09/2006	**Overall study status** Completed	
Last Edited 29/03/2012	**Condition category** Oral Health	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Not Specified

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

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

Interventions
Not provided at time of registration

Intervention Type
Device

Phase
Not Specified

Primary outcome measure

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).

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/02/2005

Completion date
30/12/2008

Eligibility

Key inclusion criteria
Population from Yorkshire

Participant type(s)
Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants
Not provided at time of registration

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
England

United Kingdom

Study participating centre

Paediatric Department
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LS2 9LU

Sponsor information

Organisation
Record Provided by the NHSTCT Register - 2006 Update - Department of Health

Sponsor details
The Department of Health, 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

Study outputs

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