

# Effect of fluoride slow-release devices on enamel remineralisation in situ

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|----------------------------------------|---------------------------------------------------|--------------------------------------------------------------------------------------------------------------|
| <b>Submission date</b><br>30/09/2004   | <b>Recruitment status</b><br>No longer recruiting | <input type="checkbox"/> Prospectively registered<br><input type="checkbox"/> Protocol                       |
| <b>Registration date</b><br>30/09/2004 | <b>Overall study status</b><br>Completed          | <input type="checkbox"/> Statistical analysis plan<br><input type="checkbox"/> Results                       |
| <b>Last Edited</b><br>30/03/2020       | <b>Condition category</b><br>Oral Health          | <input type="checkbox"/> Individual participant data<br><input type="checkbox"/> Record updated in last year |

**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**  
N0436130292

## Study information

**Scientific Title**  
Effect of fluoride slow-release devices on enamel remineralisation in situ

**Study objectives**

The aim of this study is to study the effect of fluoride slow-release devices on enamel remineralisation under cariogenic challenge using an in situ model.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

No ethics information provided at time of registration.

**Primary study design**

Interventional

**Study design**

Randomised controlled trial.

**Study type(s)**

Treatment

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

Oral Health: Cariology

**Interventions**

1. Device a
2. Device b

**Intervention Type**

Drug

**Phase**

Not Specified

**Drug/device/biological/vaccine name(s)**

Fluoride slow-release devices

**Primary outcome(s)**

Remineralisation of enamel slabs as determined using transverse microradiography and microhardness testing.

**Key secondary outcome(s)**

Not provided at time of registration

**Completion date**

02/04/2004

**Eligibility****Key inclusion criteria**

Healthy adults aged 16-65 years residing in Leeds.

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Sex**

Not Specified

**Key exclusion criteria**

Not provided at time of registration

**Date of first enrolment**

01/10/2003

**Date of final enrolment**

02/04/2004

**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)

**Results and Publications**

**Individual participant data (IPD) sharing plan**

**IPD sharing plan summary**

Not provided at time of registration