ISRCTN05340070 https://doi.org/10.1186/ISRCTN05340070

# The effect of a fluoride releasing, non-primer step required, no mix composite: A clinical trial

| Submission date | Recruitment status | [ ] Prospectively registered |
|---|---|---|
| 30/09/2004 | No longer recruiting | [ ] Protocol |
| **Registration date** | **Overall study status** | [ ] Statistical analysis plan |
| 30/09/2004 | Completed | [ ] Results |
| **Last Edited** | **Condition category** | [ ] Individual participant data |
| 28/02/2014 | Oral Health | [ ] 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

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**
N0263139746

# Study information

### Scientific Title

### Study objectives
To determine the failure rate and survival time of orthodontic bands cemented with a fluoride releasing, non-primer step required, no mix composite compared with a conventional no-mix composite and if there is a difference in demineralisation.

### 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)
Treatment

### Participant information sheet

### Health condition(s) or problem(s) studied
Oral Health: Orthodontics

### Interventions
1. Fluoride releasing, non-primer step required, no mix composite
2. Conventional no mix composite

### Intervention Type
Other

### Phase
Not Specified

### Primary outcome measure
The site and time to bond failure to be recorded for each bracket that fails over a six month period (in the first instance) and then up to the completion of treatment.

### Secondary outcome measures
Not provided at time of registration

### Overall study start date
17/03/2004

### Completion date
01/07/2007

## Eligibility

### Key inclusion criteria
Not provided at time of registration

### Participant type(s)
Patient

### Age group
Adult

### Sex
Both

### Target number of participants
50 patients from Orthodontics

### Key exclusion criteria
Not provided at time of registration

### Date of first enrolment
17/03/2004

### Date of final enrolment
01/07/2007

## Locations

### Countries of recruitment
England

United Kingdom

### Study participating centre
**Department of Orthodontics**
London
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# Sponsor information

**Organisation**
Department of Health

**Sponsor details**
Richmond House
79 Whitehall
London
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**Sponsor type**
Government

**Website**
http://www.dh.gov.uk/Home/fs/en

# Funder(s)

**Funder type**
Government

**Funder Name**
University College London Hospitals NHS Trust (UK)

# 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