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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

Protocol serial number
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

Primary study design
Interventional

Study design
Randomised controlled trial

Study type(s)
Treatment

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(s)
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.

Key secondary outcome(s)
Not provided at time of registration

Completion date
01/07/2007

Eligibility

Key inclusion criteria
Not provided at time of registration

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

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
United Kingdom

England

Study participating centre
Department of Orthodontics
London
United Kingdom
WC1X 8LD

Sponsor information

Organisation
Department of Health

Funder(s)

Funder type
Government

Funder Name

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration