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

Contact name
Miss Samantha Hodge

Contact details
Department of Orthodontics
Eastman Dental Hospital
256 Gray's Inn Road
London
United Kingdom
WC1X 8LD
+44 (0)20 7915 1000

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
United Kingdom
WC1X 8LD

Sponsor information

Organisation
Department of Health

Sponsor details
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL

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