ISRCTN35457694 https://doi.org/10.1186/ISRCTN35457694

A randomised controlled trial investigating the orthodontic bracket bond failure rates using Ortho Solo Universal bond enhancer compared to a conventional bonding primer

Submission date 30/09/2005	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 30/09/2005	**Overall study status** Completed	
Last Edited 04/08/2008	**Condition category** Oral Health	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Mr N W T Harradine

Contact details
C/O Research & Effectiveness Department
Level 1, The Old Building
Bristol Royal Infirmary
Malborough Street
Bristol
United Kingdom
BS2 8HW
+44 (0)117 928 3473
r&eoffice@ubht.swest.nhs.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N0264149441

Study information

Scientific Title

Study objectives
To investigate if a new glue system reduces the number of brackets (orthodontic brace attachments to teeth) which debond (glue fails) during treatment with fixed braces.

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

Interventions
A split mouth design will be used with right and left in the upper arch decided by random allocation with random number tables. Only incisors, canines and premolars will be included in the study.

The two types of primer to be used for bonding are the following:
1. OrthoSolo Bond enhancer
2. Transbond XT conventional adhesive

Intervention Type

Other

Phase
Not Specified

Primary outcome measure
Bond failure rate.

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/07/2004

Completion date
30/06/2008

Eligibility

Key inclusion criteria
1. Aged 16 or under
2. Both arches to be treated with fixed appliances
3. Written consent given to be included in the trial

Participant type(s)
Patient

Age group
Child

Upper age limit
16 Years

Sex
Not Specified

Target number of participants
33

Key exclusion criteria
Patients not meeting inclusion criteria.

Date of first enrolment
01/07/2004

Date of final enrolment
30/06/2008

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
C/O Research & Effectiveness Department
Bristol
United Kingdom
BS2 8HW

Sponsor information

Organisation
Department of Health

Sponsor details
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
United Bristol Healthcare NHS Trust (UK)

Funder Name

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	01/03/2008		Yes	No