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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

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Additional identifiers

Protocol serial number
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

Primary study design
Interventional

Study design
Randomised controlled trial

Study type(s)
Treatment

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(s)
Bond failure rate.

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

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

Healthy volunteers allowed
No

Age group
Child

Upper age limit
16 Years

Sex
Not Specified

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
United Kingdom

England

Study participating centre
C/O Research & Effectiveness Department
Bristol
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Sponsor information

Organisation
Department of Health

Funder(s)

Funder type
Government

Funder Name
United Bristol Healthcare NHS Trust (UK)

Funder Name
NHS R&D Support Funding (UK)

Results and Publications

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