

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
Registration date 30/09/2005	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 04/08/2008	Condition category Oral Health	☐ Individual participant data

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

Study design

Randomised controlled trial

Primary study design

Interventional

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

United Kingdom

BS2 8HW

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