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A randomised clinical trial to compare bond failure rates with and without the use of Ortho Solo

Submission date 29/09/2006	**Recruitment status** No longer recruiting	[ ] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 29/09/2006	**Overall study status** Completed	
Last Edited 20/07/2016	**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
N0158163754

Study information

Scientific Title
A randomised clinical trial to compare bond failure rates with and without the use of Ortho Solo

Study objectives
1. To determine whether there is a difference in the number of orthodontic attachments that come off the teeth with and without the use of Ortho Solo.
2. In what time frame do bond failures occur?

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: Orthodontics

Interventions
Patients are to be invited to participate if they are to have a fixed orthodontic appliance at the University Hospital of North Staffordshire Hospital NHS Trust, Orthodontic department. Consent is to be obtained by the clinician looking after the patient and with the use of a patient information sheet and consent form approved by the ethics committee. Each participant will have half the orthodontic appliance placed using the usual procedure and the other half placed with the addition of Orthosolo. This requires painting a layer of liquid onto the tooth. At each appointment the number and location of bond failures i.e. where the brace has come off the tooth, will be recorded and in this way it will be possible to compare bond failures with and without the use of Orthosolo. Where bond failure has occurred, the bracket will be replaced with the same method as previously used. At the end of the trial, the participant will continue with their routine orthodontic treatment.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
1. Number of debonds to occur in a year with and without the use of Ortho Solo
2. The time from attaching the brace to debond with and without the use of Ortho Solo

Key secondary outcome(s))

Not provided at time of registration

Completion date
01/06/2006

Eligibility

Key inclusion criteria
Any patient who is to have a fixed appliance placed at the North Staffordshire Hospital Orthodontic Department

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Not Specified

Sex
Not Specified

Key exclusion criteria
1. Enamel surfaces presenting with caries, fillings or gingival hyperplasia.
2. Molar brackets

Date of first enrolment
01/01/2005

Date of final enrolment
01/06/2006

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
University Hospital of North Staffordshire
Stoke-on-Trent
United Kingdom
ST4 7PA

Sponsor information

Organisation
Record Provided by the NHSTCT Register - 2006 Update - Department of Health

Funder(s)

Funder type
Government

Funder Name
North Staffordshire Research and Development Consortium (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration