

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
Registration date 29/09/2006	Overall study status Completed	☐ Statistical analysis plan ☐ Results
Last Edited 20/07/2016	Condition category Oral Health	☐ Individual participant data ☐ Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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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

Primary study design

Interventional

Study design

Randomised controlled trial

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