

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

<b>Submission date</b> 29/09/2006	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 29/09/2006	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 20/07/2016	<b>Condition category</b> Oral Health	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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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### Contact details

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## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

## Secondary identifying numbers

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

## Secondary study design

Randomised controlled trial

## Study setting(s)

Hospital

## Study type(s)

Treatment

## Participant information sheet

## 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 measure**

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

**Secondary outcome measures**

Not provided at time of registration

**Overall study start date**

01/01/2005

**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

**Age group**

Not Specified

**Sex**

Not Specified

**Target number of participants**

Not provided at time of registration

**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

England

United Kingdom

## 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

## Sponsor details

The Department of Health, 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

North Staffordshire Research and Development Consortium (UK)

# 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