

# A randomised prospective clinical trial to compare two different methods of applying a new resin-reinforced chemically-cured "moisture-friendly" glass ionomer cement for the bonding of orthodontic brackets

<b>Submission date</b> 12/09/2003	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 12/09/2003	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 17/12/2019	<b>Condition category</b> Oral Health	<input type="checkbox"/> 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

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**

N0436121385

## **Study information**

### **Scientific Title**

A randomised prospective clinical trial to compare two different methods of applying a new resin-reinforced chemically-cured "moisture-friendly" glass ionomer cement for the bonding of orthodontic brackets

### **Study objectives**

The study will be used to investigate the clinical failure rate, using the survival rate analysis, of orthodontic brackets bonded using a new resin-reinforced, chemically cured "moisture-friendly" glass ionomer cement by two recommended methods.

### **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**

Dental Materials

### **Interventions**

Randomised controlled trial. Random allocation to:

A. Method 1

B. Method 2

**Intervention Type**

Other

**Phase**

Not Specified

**Primary outcome measure**

1. Bracket survival
2. Tooth type, e.g. incisor canine premolar versus debond incidence
3. Adhesive Remnant Index assessment score
4. Chairside cleanup time

**Secondary outcome measures**

Not provided at time of registration

**Overall study start date**

01/10/2001

**Completion date**

01/10/2003

**Eligibility****Key inclusion criteria**

60 Consecutive healthy subjects aged between 10-18 years from the orthodontic treatment waiting list at St James's Hospital requiring orthodontic treatment with upper and lower fixed appliances will be randomly allocated to the two study groups.

**Participant type(s)**

Patient

**Age group**

Child

**Lower age limit**

10 Years

**Upper age limit**

18 Years

**Sex**

Both

**Target number of participants**

60

**Total final enrolment**

49

**Key exclusion criteria**

Not provided at time of registration

**Date of first enrolment**

01/10/2001

**Date of final enrolment**

01/10/2003

## **Locations**

**Countries of recruitment**

England

United Kingdom

**Study participating centre**

**Oral and Maxillo-facial Surgery**

Leeds

United Kingdom

LS9 7TF

## **Sponsor information**

**Organisation**

Department of Health (UK)

**Sponsor details**

Richmond House

79 Whitehall

London

United Kingdom

SW1A 2NL

**Sponsor type**

Government

**Website**

<http://www.doh.gov.uk>

## **Funder(s)**

**Funder type**

Hospital/treatment centre

**Funder Name**

Leeds Teaching Hospitals NHS Trust (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

**Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Abstract results</a>	A clinical trial of Fuji ORTHO glass ionomer for orthodontic bonding	01/06/2005	17/12/2019	No	No
<a href="#">Abstract results</a>	abstract page 140-141	01/06/2005	17/12/2019	No	No