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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

Submission date 12/09/2003	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 12/09/2003	**Overall study status** Completed	
Last Edited 17/12/2019	**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

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?
Abstract results	A clinical trial of Fuji ORTHO glass ionomer for orthodontic bonding	01/06/2005	17/12/2019	No	No
Abstract results	abstract page 140-141	01/06/2005	17/12/2019	No	No