

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
Registration date 12/09/2003	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 17/12/2019	Condition category Oral Health	☐ Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Mr DO Morris

Contact details
Oral and Maxillo-facial Surgery
Chancellor Wing
St James's University Hospital
Beckett Street
Leeds
United Kingdom
LS9 7TF
+44 (0)113 206 3697
david.morris@leedsth.nhs.uk

Additional identifiers

Protocol serial number
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

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

Not provided at time of registration

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

Healthy volunteers allowed

No

Age group

Child

Lower age limit

10 Years

Upper age limit

18 Years

Sex

All

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

United Kingdom

England

Study participating centre

Oral and Maxillo-facial Surgery
Leeds
United Kingdom
LS9 7TF

Sponsor information

Organisation
Department of Health (UK)

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Leeds Teaching Hospitals NHS Trust (UK)

Results and Publications

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