ISRCTN70334837 https://doi.org/10.1186/ISRCTN70334837

A clinical and laboratory study of the performance of a dual-cured glass-ionomer cement as a bonding agent for orthodontic brackets.

Submission date
23/01/2004

Recruitment status
No longer recruiting

Registration date
23/01/2004

Overall study status
Completed

Last Edited
18/01/2010

Condition category
Oral Health

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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
94060005

Study information

Scientific Title

Study objectives
To assess the clinical performance of a resin-modified glass ionomer cement as an orthodontic bonding agent, and to compare these findings with the results of laboratory tests of bond performance.

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)
Other

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Oral health/stomatognathic diseases

Interventions
Each patient will be allocated randomly to one of three test groups :
1. Glass-ionomer without sandblasting vs. composite resin
2. Glass-ionomer with sandblasting vs. composite resin
3. Glass-ionomer with sandblasting vs. glass-ionomer without sandblasting

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Clinical bracket failure rates. In vitro: bracket bond strengths and fatigue (assessed using a ball mill); fluoride release over time

Secondary outcome measures
Not provided at time of registration

Overall study start date
04/01/1994

Completion date
04/01/1996

Eligibility

Key inclusion criteria
Patients attending for routine orthodontic treatment using fixed appliances.

Participant type(s)
Patient

Age group
Other

Sex
Both

Target number of participants
Not provided at time of registration

Key exclusion criteria
Does not match inclusion criteria

Date of first enrolment
04/01/1994

Date of final enrolment
04/01/1996

Locations

Countries of recruitment
England

United Kingdom

Study participating centre

Dental School
Newcastle upon Tyne
United Kingdom
NE2 4BW

Sponsor information

Organisation
NHS R&D Regional Programme Register - Department of Health (UK)

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.doh.gov.uk

Funder(s)

Funder type
Government

Funder Name
NHS Executive Northern and Yorkshire (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?
Results article	results	01/05/1995		Yes	No