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

Submission date	Recruitment status No longer recruiting	Prospectively registered		
23/01/2004		☐ Protocol		
Registration date	Overall study status	Statistical analysis plan		
23/01/2004	Completed	[X] Results		
Last Edited 18/01/2010	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

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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 summaryNot 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