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A randomised controlled trial comparing conventional, active and passive self-ligating orthodontic bracket systems

Submission date 28/09/2007	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 28/09/2007	**Overall study status** Completed	
Last Edited 13/04/2018	**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

Protocol serial number
N0249180873

Study information

Scientific Title

A randomised controlled trial comparing conventional, active and passive self-ligating orthodontic bracket systems

Study objectives
Do any of three routinely used brackets show superiority in terms of faster overall treatment time for patient and chairside time for clinicians?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Somerset Research Ethics Committee (UK), 08/03/2006, REC ref: 06/Q2202/6

Study design
Double-blind randomised controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Oral Health: Orthodontics

Interventions
1. Standard GAC Omni bracket
2. System R GAC Omni bracket
3. Damon bracket

Intervention Type
Other

Phase
Not Specified

Primary outcome(s)
Before September 2008: time to alignment, chairside time.
Modified September 2008: overall treatment time and chairside time.

Key secondary outcome(s))
Added September 2008: time to initial alignment and time for space closure.

Completion date
01/04/2009

Eligibility

Key inclusion criteria
100 children under 18 requiring routine upper and lower fixed appliances following extraction.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Child

Upper age limit
18 years

Sex
All

Key exclusion criteria
1. Subjects with learning difficulties
2. Subjects who do not understand English
3. Subjects with incomplete labial segments, i.e. incisors or canines missing

Date of first enrolment
01/03/2006

Date of final enrolment
01/04/2009

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Taunton & Somerset Hospital
Taunton
United Kingdom
TA1 5DA

Sponsor information

Organisation
Record Provided by the NHSTCT Register - 2007 Update - Department of Health

Funder(s)

Funder type
Government

Funder Name
Taunton and Somerset Research and Development Consortium (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?
Results article	results	01/05/2014		Yes	No