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

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Miss Nikki Atack

Contact details
Department of Orthodontics
Taunton & Somerset Hospital
Musgrove Park
Taunton
United Kingdom
TA1 5DA
+44 (0)1823 342136
nicola.atack@tst.nhs.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

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 measure
Before September 2008: time to alignment, chairside time.
Modified September 2008: overall treatment time and chairside time.

Secondary outcome measures
Added September 2008: time to initial alignment and time for space closure.

Overall study start date
01/03/2006

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

Age group
Child

Upper age limit
18 Years

Sex
Both

Target number of participants
100

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
England

United Kingdom

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

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.dh.gov.uk/Home/fs/en

Funder(s)

Funder type
Government

Funder Name
Taunton and Somerset Research and Development Consortium (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	01/05/2014		Yes	No