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A prospective randomized trial investigating the alignment efficiency of two pre-adjusted edgewise orthodontic bracket systems

Submission date 30/09/2005	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 30/09/2005	**Overall study status** Completed	
Last Edited 12/04/2011	**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
N0013154732

Study information

Scientific Title

Study objectives
Recently a ligature free orthodontic bracket system has been introduced. It has been suggested that reduced friction associated with this system can provide considerable benefits to the patient, principally because the teeth align more rapidly. We propose to investigate the alignment rate of two fixed orthodontic vracked systems; Ormco Damon-2 self -ligating and Ormco Synthesis conventional siamese.

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)
Not Specified

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

Interventions
A Prospective Randomised Controlled Clinical Trial comparing Ormco Damon 2 ligature free bracket system and Ormco conventional pre-adjusted edgewise bracket system. The patients will be given a "pain diary " to complete and they will be reviewed six weekly. Patients will be randomly allocated to one of the two groups.

Intervention Type
Other

Phase
Not Specified

Primary outcome(s)
1. Speed of alignment of the lower labial segment
2. Self reported pain or discomfort and root resorption of lower central incisors

Key secondary outcome(s)
Not provided at time of registration

Completion date
30/11/2006

Eligibility

Key inclusion criteria
Children under the age of 16, fit and well and not taking any medication; who present with a crowded dentition that require extraction of first pre-molars and fixed appliance therapy. 30 patients at Guy's and 30 at Canterbury.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Child

Upper age limit
16 Years

Sex
Not Specified

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
08/11/2004

Date of final enrolment
30/11/2006

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Department of Orthodontics
London
United Kingdom
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Sponsor information

Organisation
Department of Health

Funder(s)

Funder type
Government

Funder Name
Guy's and St. Thomas' NHS Foundation Trust (UK)

Funder Name
Own account

Funder Name
NHS R&D Support Funding

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	01/06/2008		Yes	No