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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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Not Specified

Participant information sheet

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 measure
1. Speed of alignment of the lower labial segment
2. Self reported pain or discomfort and root resorption of lower central incisors

Secondary outcome measures
Not provided at time of registration

Overall study start date
08/11/2004

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

Age group
Child

Upper age limit
16 Years

Sex
Not Specified

Target number of participants
60

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
England

United Kingdom

Study participating centre
Department of Orthodontics
London
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Sponsor information

Organisation
Department of Health

Sponsor details
Richmond House
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Sponsor type
Government

Website
http://www.dh.gov.uk/Home/fs/en

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

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	01/06/2008		Yes	No