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

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

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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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
United Kingdom

SE1 9RT

Sponsor information

Organisation

Department of Health

Sponsor details

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

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

Funder Name

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