ISRCTN05296896 https://doi.org/10.1186/ISRCTN05296896

A prospective randomised clinical trial to compare pain levels of two orthodontic fixed bracket systems

Submission date
13/03/2005

Recruitment status
No longer recruiting

Registration date
31/03/2005

Overall study status
Completed

Last Edited
29/01/2010

Condition category
Oral Health

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

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
N/A

Study information

Scientific Title

Study objectives
Pain is frequently experienced by patients, particularly during the early stages of orthodontic treatment, when the teeth are being moved. The pain is thought to be due to forces applied to the teeth during tooth movement with orthodontic fixed appliances or "braces". Pain experienced is unpredictable and usually peaks at 48 to 72 hours after the brace has been adjusted. Not all patients complete their orthodontic treatment because of the pain experienced at the start of treatment. An alternative type of fixed orthodontic bracket has been designed which the manufacturers claim is less painful to the patient during treatment. However, there is no independent evidence to support this finding. The
bracket passively holds the orthodontic wire in position and is said to reduce friction. The standard orthodontic bracket holds the wire in position using small elastic bands which impart more friction, therefore more force is needed to overcome the friction and move the tooth. The aim of this study is to establish whether the new type of orthodontic bracket results in less pain for the patient. Secondarily it will establish whether the treatment duration is reduced, whether space closure between teeth is faster and whether the time taken to adjust the brace is reduced.
Null Hypothesis: there is no difference in pain experienced by patients when comparing the true straight orthodontic bracket and the Damon bracket
Study Hypothesis: patients experience less pain during fixed orthodontic treatment using the Damon bracket as compared with the true straight bracket.

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)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Pain levels during orthodontic treatment

Interventions
Randomisation of treatment to two fixed appliance systems - true straight bracket and the Damon bracket. Comparing pain levels, rate of space closure when teeth have been extracted, treatment duration.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Does an alternative design of orthodontic fixed brace result in less pain for the patients during orthodontic treatment?

Secondary outcome measures
Does the alternative orthodontic brace reduce treatment duration?
Does the alternative orthodontic brace allow space between teeth to be closed faster than the conventional orthodontic brace when teeth have been extracted?
Is the alternative orthodontic brace quicker and easier to adjust during treatment?

Overall study start date
01/06/2005

Completion date
30/06/2008

Eligibility

Key inclusion criteria
Patients requiring orthodontic treatment with fixed appliances

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
112

Key exclusion criteria
1. Those patients under the age of 16 will only be asked if they are accompanied by a parent or legal guardian
2. Patient undergoing active headgear treatment

3. Patients undergoing maxillary expansion with either quadhelix, rapid maxillary expansion device or a upper removable appliance with midline expansion screw
4. Patients unable to speak English will unfortunately have to be excluded from the study as it will be difficult to ensure that exactly the same information is provided in all languages even with the benefit of professional interpreting staff

Date of first enrolment
01/06/2005

Date of final enrolment
30/06/2008

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Department of Oral and Maxillofacial Surgery and Orthodontics
Oxford
United Kingdom
OX3 9DU

Sponsor information

Organisation
Oxford Radcliffe Hospitals NHS Trust (UK)

Sponsor details
Department of Oral and Maxillofacial Surgery and Orthodontics
The John Radcliffe
Headley Way
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England
United Kingdom
OX3 9DU

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/03h2bh287

Funder(s)

Funder type
Government

Funder Name
Oxford Radcliffe Hospitals NHS Trust (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	01/08/2009		Yes	No