

Prospective comparative study of affects of two functional appliances

Submission date 30/09/2005	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 30/09/2005	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 14/03/2014	Condition category Oral Health	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

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
N0514153013

Study information

Scientific Title

Study objectives

To study effects of treatment of patients with Class II DW I malocclusion with modified Clarke Twin block appliance and Bass Dynamax appliance.

Ethics approval required

Old ethics approval format

Ethics approval(s)

East Kent Local Research Ethics Committee, 06/11/2008, ref: 08/H1103/66

Study design

Randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Not Specified

Participant information sheet

Health condition(s) or problem(s) studied

Oral Health

Interventions

2 appliance systems (Twin Block and Dynamax)

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

1. Hard tissue changes from lateral cephalo mexric radiograph taken at start and end of treatment.
2. Soft tissue changes from 3D laser scans taken during treatment

Secondary outcome measures

Not provided at time of registration

Overall study start date

01/10/2004

Completion date

30/09/2007

Eligibility

Key inclusion criteria

200 patients awaiting treatment on orthodontic waiting lists to be allocated into one of the two groups. Inclusion criteria:

1. Class II division 1 malocclusion on a skeletal II base
2. Mandibular retrusion contributing to the skeletal II base
3. Minimum overjet of 7mm
4. Male caucasians aged 12-14 years by Jan 1st 2003
5. Female caucasians aged 10-13 years by Jan 1st 2003
6. No history of orthodontic treatment
7. No permanent tooth extractions
8. No relevant medical history

Participant type(s)

Patient

Age group

Child

Lower age limit

10 Years

Upper age limit

14 Years

Sex

Both

Target number of participants

200

Key exclusion criteria

If patients don't fit in to the inclusion criteria defined above then they were not included in the study.

Date of first enrolment

01/10/2004

Date of final enrolment

30/09/2007

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

East Kent Hospitals NHS Trust

Canterbury

United Kingdom

CT1 3NG

Sponsor information

Organisation

Department of Health

Sponsor details

Richmond House

79 Whitehall

London

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SW1A 2NL

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Sponsor type

Government

Website

<http://www.dh.gov.uk/Home/fs/en>

Funder(s)

Funder type

Government

Funder Name

East Kent Hospitals NHS Trust (UK)

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