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Prospective comparative study of affects of two functional appliances

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	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
14/03/2014	Oral Health	[ ] 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. Madibular retrongnathia 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
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SW1A 2NL
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dhmail@doh.gsi.org.uk

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