ISRCTN52655400 https://doi.org/10.1186/ISRCTN52655400

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

Protocol serial number
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

Study type(s)
Not Specified

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(s)
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

Key secondary outcome(s))
Not provided at time of registration

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

Healthy volunteers allowed
No

Age group
Child

Lower age limit
10 years

Upper age limit
14 years

Sex
All

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
United Kingdom

England

Study participating centre
East Kent Hospitals NHS Trust
Canterbury
United Kingdom
CT1 3NG

Sponsor information

Organisation
Department of Health

Funder(s)

Funder type
Government

Funder Name
East Kent Hospitals NHS Trust (UK)

Funder Name
NHS R&D Support Funding

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration