

Prospective comparative study of affects of two functional appliances

Submission date 30/09/2005	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 30/09/2005	Overall study status Completed	☐ Statistical analysis plan ☐ Results
Last Edited 14/03/2014	Condition category Oral Health	☐ Individual participant data ☐ 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 cephalometric 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. 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

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