

The influence of clasp design on twin block appliances outcome - a prospective randomised, controlled clinical trial

Submission date 12/09/2003	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 12/09/2003	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 15/05/2013	Condition category Oral Health	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N0188119744

Study information

Scientific Title

Study objectives

To discover if incorporating a Southend Clasp on the upper central incisors in the design of the Twin Block Appliance will eliminate or greatly reduce incisor retraction thereby enhancing mandibular advancement.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Added May 2008: Preston and Chorley and South Ribble Research Ethics Committee on 03/07 /2003

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

Not available in web format, please use the contact details below to request a patient information sheet.

Health condition(s) or problem(s) studied

Oral Health: Orthodontics

Interventions

Random allocation of two alternative designs of twin block appliance, one with a Southend clasp on the upper central incisors and one without. The appliances are identical in all other aspects.

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

Added May 2008:

Angulation of the long axis of the upper incisor to the maxillary plane, as measured from a lateral cephalometric radiograph.

Secondary outcome measures

Added May 2008:

1. Angulation of the long axis of the lower incisor to the mandibular plane
2. Skeletal relationship as measured by angle ANB

Overall study start date

01/01/2003

Completion date

01/04/2007

Eligibility

Key inclusion criteria

1. Patients aged 11-15 years
2. Added May 2008: with Class II division 1 malocclusion suitable for functional appliance therapy. The overjet had to be greater than 6mm and ANB angle greater than 4°.

Participant type(s)

Patient

Age group

Child

Lower age limit

11 Years

Upper age limit

15 Years

Sex

Not Specified

Target number of participants

102. Corrected May 2008: 52. Added October 2009: recruitment completed and analysis ongoing.

Key exclusion criteria

Added May 2008:

Patients with congenital syndromes, obvious asymmetry and prior appliance therapy were excluded.

Date of first enrolment

01/01/2003

Date of final enrolment

01/04/2007

Locations

Countries of recruitment

England

United Kingdom

Study participating centre**Consultant Orthodontist**

Preston

United Kingdom

PR2 9HT

Sponsor information

Organisation

Department of Health (UK)

Sponsor details

Richmond House

79 Whitehall

London

United Kingdom

SW1A 2NL

Sponsor type

Government

Website

<http://www.doh.gov.uk>

Funder(s)

Funder type

Government

Funder Name

Lancashire Teaching 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	01/03/2012		Yes	No