

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

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

Dr MJ Trenouth

### Contact details

Consultant Orthodontist  
Royal Preston Hospital  
Sharoe Green Lane North  
Fulwood  
Preston  
United Kingdom  
PR2 9HT  
+44 (0)1772 523150  
michaeltrenouth@hotmail.co.uk

## 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?
<a href="#">Results article</a>	results	01/03/2012		Yes	No