

# 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](mailto:michaeltrenouth@hotmail.co.uk)

## Additional identifiers

### Protocol serial number

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

### **Study type(s)**

Not Specified

### **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(s)**

Added May 2008:

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

### **Key secondary outcome(s)**

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

### **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

## Healthy volunteers allowed

No

## Age group

Child

## Lower age limit

11 years

## Upper age limit

15 years

## Sex

Not Specified

## 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

United Kingdom

England

## Study participating centre

Consultant Orthodontist

Preston

United Kingdom

PR2 9HT

# Sponsor information

## Organisation

Department of Health (UK)

## Funder(s)

### Funder type

Government

### Funder Name

Lancashire Teaching Hospitals NHS Trust (UK)

# Results and Publications

## 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
<a href="#">Participant information sheet</a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes