

# The effectiveness of non-surgical orthodontic treatment for the treatment of severe class II growth anomalies

<b>Submission date</b> 17/10/2000	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 17/10/2000	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
<b>Last Edited</b> 17/07/2012	<b>Condition category</b> Oral Health	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

Professor Kevin O'Brien

### Contact details

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## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

G9410454

# Study information

## Scientific Title

### Study objectives

To evaluate the effectiveness of different methods of orthodontic growth modification for the treatment of mandibular deficiency. The methods that are being compared are: (1) Early treatment with a Twin Block appliance and no treatment (2) Later treatment with a Herbst appliance or a Twin Block.

This trial was continued by ISRCTN26364810 - grant G9901331.

### Ethics approval required

Old ethics approval format

### Ethics approval(s)

Not provided at time of registration

### Study design

Randomised controlled trial

### Primary study design

Interventional

### Secondary study design

Randomised controlled trial

### Study setting(s)

Not specified

### Study type(s)

Not Specified

## Participant information sheet

### Health condition(s) or problem(s) studied

Dental

### Interventions

Early treatment with a Twin Block appliance and no treatment.  
Later treatment with a Herbst appliance or a Twin Block.

This trial was continued by ISRCTN26364810 - grant G9901331.

### Intervention Type

Other

### Phase

Not Specified

**Primary outcome measure**

Dental and skeletal change, self esteem and patient preference

**Secondary outcome measures**

Not provided at time of registration

**Overall study start date**

01/04/1997

**Completion date**

01/04/2001

## Eligibility

**Key inclusion criteria**

Children with an overjet of greater than 7 mm

**Participant type(s)**

Patient

**Age group**

Child

**Sex**

Not Specified

**Target number of participants**

480 Added 20/08/09: 2 years follow-up

**Key exclusion criteria**

Craniofacial syndrome

**Date of first enrolment**

01/04/1997

**Date of final enrolment**

01/04/2001

## Locations

**Countries of recruitment**

England

United Kingdom

**Study participating centre**

Department of Dental Medicine and Surgery

Manchester

United Kingdom  
M15 6FH

## Sponsor information

### Organisation

Medical Research Council (MRC) (UK)

### Sponsor details

20 Park Crescent  
London  
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W1B 1AL  
+44 (0)20 7636 5422  
[clinical.trial@headoffice.mrc.ac.uk](mailto:clinical.trial@headoffice.mrc.ac.uk)

### Sponsor type

Research council

### Website

<http://www.mrc.ac.uk>

## Funder(s)

### Funder type

Research council

### Funder Name

Medical Research Council (MRC) (UK)

### Alternative Name(s)

Medical Research Council (United Kingdom), UK Medical Research Council, MRC

### Funding Body Type

Government organisation

### Funding Body Subtype

National government

### Location

United Kingdom

# 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