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

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

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

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

Sponsor information

Organisation

Medical Research Council (MRC) (UK)

Sponsor details

20 Park Crescent London United Kingdom W1B 1AL +44 (0)20 7636 5422 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 planNot provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summaryNot provided at time of registration