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The long-term effects of orthodontic growth modification for severe Class II anomalies

Submission date 19/01/2001	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 19/01/2001	**Overall study status** Completed	
Last Edited 07/09/2009	**Condition category** Oral Health	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
G9901331

Study information

Scientific Title

Study objectives
The proposed study is a follow-up to an existing MRC funded study into orthodontic growth modification treatment for Class II skeletal malocclusion, which:
1. Investigated early orthodontic intervention compared to a control group
2. Compared two orthodontic appliances in later intervention

The proposed study aims to
1. Compare early treatment patients and controls after any subsequent treatment received, to evaluate the long-term benefits/drawbacks of treatment timing
2. Evaluate the long-term effects of the appliances in the existing study
3. Start a new trial to compare the effect of two types of post-treatment retention on Class II patients who have finished orthodontic growth modification treatment

ISRCTN61138858 - grant G9410454 preceded this trial.

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
Study 1: Early orthodontic treatment with Twin Block or untreated control
Study 2: Orthodontic treatment with a Twin Block or a Herbst appliance
Study 3: Orthodontic treatment with a Twin Block appliance randomised to fixed or removable orthodontic retention

ISRCTN61138858 - grant G9410454 preceded this trial.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Study 1
Children in the early group, already randomised to treatment or control, will be treated where necessary according to the protocol of the consultant. Records will be taken at the end of all treatment or after 5 years if there has been no treatment. The outcomes will be:
- Whether further treatment was needed.
- If treatment was needed.
- Duration of treatment.
- Did the treatment involve jaw surgery?
- The number of visits required to complete treatment.
- Dental change, recorded from study model analysis with the PAR index.
- Skeletal and Dental change, measured with cephalometric analysis.
- Change in patient perceptions with Piers Harris self-esteem measure.
- The cost of the treatment
- Trauma to the incisors?

Study 2
Patients already randomised to treatment with a Herbst or a Twin Block appliance (treatment now completed) will be followed up for a period of 5 years and the following outcome measures will be collected:
- Skeletal and dental change, measured with cephalometric analysis.
- Dental change, recorded from study model analysis with the PAR index.
- Change in patient perceptions with Piers Harris self-esteem measure.

Study 3
Patients finishing growth modification treatment with a Twin Block appliance will be randomised to two groups. One group will be given upper and lower removable retaining appliances, the other will have fixed retaining appliances fitted to the inside of their anterior teeth. Outcomes:
- Skeletal and dental change, measured with cephalometric analysis.
- Dental change, recorded from study model analysis with the PAR index.
- Change in patient perceptions with Piers Harris self-esteem measure.

Secondary outcome measures
Not provided at time of registration.

Overall study start date
01/04/2001

Completion date
30/09/2006

Eligibility

Key inclusion criteria
Studies 1 and 2 : Initial Dental overjet of greater than 7 mm; enrolment in the original Class II study.

Study 3: The patient has received Twin Block treatment followed by upper and lower fixed appliances; the original overjet was greater than or equal to 7 mm; any operator in the department provided treatment.

Participant type(s)
Patient

Age group
Child

Sex
Not Specified

Target number of participants
Study 1=160, Study 2=166, Study 3=160, Total=486

Key exclusion criteria
Studies 1 and 2: Initial dental overjet of less than 7 mm; enrolment in the original Class II Study.

Study 3: Individuals with clefts of the lip and/or palate or any other suspected identifiable syndromes; people with midline diastema not caused by incisor proclination; people with hypodontia; treatment discontinued early/poor oral hygiene.

Date of first enrolment
01/04/2001

Date of final enrolment
30/09/2006

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Department of Dental Medicine and Surgery
Manchester
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Sponsor information

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University of Manchester (UK)

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Sponsor type
University/education

Website
http://www.manchester.ac.uk/

ROR
https://ror.org/027m9bs27

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results of Study 1	01/09/2003		Yes	No