ISRCTN10014340 https://doi.org/10.1186/ISRCTN10014340

Early orthodontic treatment for reverse bite: an orthopaedic facemask treatment for children < 10 years old reduces the need for jaw surgery in the late teens

Submission date
22/04/2016

Recruitment status
No longer recruiting

Registration date
12/05/2016

Overall study status
Completed

Last Edited
20/01/2020

Condition category
Oral Health

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Class III malocclusion is where the lower jaw is larger and lies ahead of the top jaw, resulting in a reverse bite. Around 3-8% of European children have this sort of bite. It may result in difficulty biting food and children are often teased about their facial appearance. The management of severe class III cases often involves surgery. Around 2,500 teenagers have jaw surgery per year, of which 60% will be for class III problems. This costs around £13.5 million. Additionally, there are the risks of general anaesthesia and surgery, and injury to the nerve supplying feeling /sensation to the lower lip and chin. There is a treatment involving a facemask brace which is used to pull the top jaw and teeth forwards with elastics. This only works in children under 10 years old. They wear the facemask brace at night for about 8 months. As clinicians we need to decide whether to treat children at a young age with the facemask brace or simply to observe their jaw growth and treat them with facial surgery when they are 16 years old. There is not enough evidence about the long-term effects of the facemask brace and whether it would reduce the need for jaw surgery in the teenage years. Therefore the main focus of our study is to see whether early brace treatment means that a child does not need jaw surgery later.

Who can participate?
Patients aged 7-9 with class III malocclusion

What does the study involve?
Participants are randomly allocated to receive either facemask brace treatment or no treatment. All participants are followed up for 6 years to assess whether their reverse bite is corrected or whether they need jaw surgery.

What are the possible benefits and risks of participating?
Correction of the reverse bite at an early age might reduce the amount of orthodontic

treatment or jaw surgery treatment that may be required later. There are no addition risks of participating – there is the routine risk of decalcification of the enamel around the brace if the teeth are not kept clean or if the patient has a high sugar diet.

Where is the study run from?
Tameside Hospital NHS Foundation Trust (lead site) (UK)

When is the study starting and how long is it expected to run for?
January 2004 to April 2014

Who is funding the study?
1. British Orthodontic Society (UK)
2. TP Orthodontics Europe

Who is the main contact?
Dr Nicky Mandall
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title

Early class III protraction facemask treatment reduces the need for orthognathic surgery: a multicentre, two-arm, parallel randomised controlled trial

Acronym
Early class III trial

Study objectives
The null hypotheses stated that early class III protraction facemask did not reduce the need for orthognathic surgery and that there were no differences between treated patients (Protraction Facemask Group, PFG) and the untreated/control group (CG) in terms of skeletal and occlusal changes, self-esteem and oral aesthetic impact of malocclusion.

Ethics approval required
Old ethics approval format

Ethics approval(s)
North West MREC, 18/02/2003, MREC 03/8/2

Study design
Interventional multi-centre randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

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
Class III reverse bite with a class III skeletal face profile (small upper jaw and large lower jaw)

Interventions
Random allocation to protraction facemask treatment or no treatment/control groups.

The intervention was a protraction facemask treatment which is a head brace attached to an upper plastic brace. The upper plastic brace is cemented to the upper teeth. Elastics are attached from the plastic brace in the mouth to the head brace. The elastics and head brace are worn at night for about 8 months and this gradually corrects the reverse bite.

Intervention Type
Device

Primary outcome measure
1. Need for orthognathic surgery: measured at 6 year follow-up using expert panel consensus
2. Skeletal change: measured from lateral cephalogram facial radiographs at 15 months, 3 years and 6 years follow-up
3. Dental change, correction of reverse bite: measured from dental models at 15 months, 3 years and 6 years follow-up

Secondary outcome measures
1. Self esteem: using Piers Harris questionnaire at 15 months, 3 years and 6 years follow-up
2. Oral aesthetic impact: using OASIS questionnaire at 15 months, 3 years and 6 years follow-up
3. Temporomandibular joint signs or symptoms: clinical examination at 15 months and 3 years

Overall study start date
01/01/2004

Completion date
01/04/2014

Eligibility

Key inclusion criteria
1. 7-9 years old
2. Class III skeletal pattern
3. 3 or 4 incisors in crossbite

Participant type(s)
Patient

Age group
Child

Lower age limit
7 Years

Upper age limit
9 Years

Sex
Both

Target number of participants
Target = 46. Over recruitment n=73 to allow for dropouts. Final sample size = 65

Key exclusion criteria
1. Non-white Caucasian origin
2. Cleft lip and or palate or craniofacial syndrome
3. Maxillomandibular plane angle of more than 35 degrees
4. Lower face height greater than 70 mm
5. Previous temporomandibular pain dysfunction syndrome

Date of first enrolment
01/01/2004

Date of final enrolment
01/12/2006

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Tameside Hospital NHS Foundation Trust (lead site)
United Kingdom
OL6 9RW

Study participating centre
St Luke's Hospital
Bradford
United Kingdom
BD5 ONA

Study participating centre
Peterborough Hospital
United Kingdom
PE3 9GZ

Study participating centre
Kent and Canterbury Hospital
United Kingdom
CT1 3NG

Study participating centre
Newcastle Dental Hospital
United Kingdom
NE2 4AZ

Study participating centre
Charles Clifford Dental Hospital
United Kingdom
S10 2SZ

Study participating centre
Southend Hospital
United Kingdom
SSO ORY

Sponsor information

Organisation
Tameside Hospital NHS Foundation Trust (UK)

Sponsor details
Fountain Street
Ashton under Lyne
England
United Kingdom
OL6 9RW

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/01knk7v72

Funder(s)

Funder type
Industry

Funder Name
British Orthodontic Society (UK)

Funder Name
TP Orthodontics Europe

Results and Publications

Publication and dissemination plan

Intention to publish date
01/05/2016

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results (15 months follow-up)	01/09/2010		Yes	No
Results article	results (3 years follow-up)	01/09/2012		Yes	No
Results article	results (6 years follow-up)	01/09/2016		Yes	No