ISRCTN20400513 https://doi.org/10.1186/ISRCTN20400513

The effectiveness of an orthodontic brace for a receding chin

Submission date	Recruitment status	[ ] Prospectively registered
30/05/2013	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
12/06/2013	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
23/06/2021	Oral Health	[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Children with small lower jaws and prominent upper front teeth represent about one third of the workload of British Orthodontists. The braces aim to reduce the prominence of the teeth by bringing the lower jaw forward to 'catch up' with the upper jaw. This treatment reduces the risk of damage to the upper teeth and improves the bite (eating) in some cases. The orthodontic brace used to correct the small lower jaw and prominent upper teeth is called a 'twinblock'. This brace has been in used for over 30 years and is used widely on growing children between around 10 1/2 and 15 years old. If an orthodontist was asked whether the twinblock works best on a 10.5 year old or a 15 year old they would be unsure of the correct answer. This is because there is no research to help with the decision. Therefore, this study has two groups, an earlier and a later group where the earlier group starts treatment straight away and the later group waits until they are 18 months older. The aim of the treatment is to assess how well the twinblock brace works comparing the earlier and later groups. We will measure jaw and tooth improvements and also self esteem and how patients feel about their teeth.

Who can participate?
Boy or a girl, age 10.5 - 13.5 years. You can take part if you have a small lower jaw and top front teeth that 'stick out'. You will need to be happy to wear the brace.

What does the study involve?
The treatment is with a twinblock brace. It is plastic two part top and bottom brace that clips over your teeth. You would wear the brace for 18 months. All the people taking part will have the same design of twinblock brace. You will be randomly allocated to two groups. The difference is when you have your treatment, group 1 means you have the brace straight away, group 2 means that you wait 18 months until you are a little older.

What are the possible benefits and risks of participating?
The quality of your brace treatment is the same whether you enrol in study or not. Usually for the twinblock brace there is a waiting list of 18 months or longer. So if you are in the later treatment group there is no difference in the time you wait. You may be in the immediate

treatment group and start your brace quicker. There are no side effects to the treatment except some mild discomfort that you normally have with the twinblock braces. Paracetamol or headache tablets will take away any tooth or jaw ache.

Where is the study run from?
The study is run from Tameside Hospital NHS, Foundation Trust, Manchester UK, and this is the lead centre. There are two other hospitals taking part these are St Lukes Hospital Bradford UK and University Hospital of NorthStaffordshire UK.

When is the study starting and how long is it expected to run for?
The study has started at the lead centre in December 2011. The duration of the trial is 6 years. When the additional two hospitals sites are recruiting it is expected that the recruitment will be completed by December 2014.

Who is funding the study?
Tameside Hospital NHS Foundation Trust (UK)

Who is the main contact?
Dr Nicky Mandall
Nicky.mandall@tgh.nhs.uk

Contact information

Type(s)
Scientific

Contact name
Dr Nicky Mandall

Contact details
Tameside Hospital NHS Foundation Trust
Fountain Street
Ashton under Lyne
Greater Manchester
United Kingdom
OL6 9RW
+44 (0)161 331 6383
Nicky.mandall@tgh.nhs.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
version 1 Date 26.4.2011

Study information

Scientific Title
A randomised controlled trial to compare the effect of a twinblock brace to correct a receding chin with a delayed treatment/control group

Acronym
C2C

Study objectives
There is no difference in the effectiveness of a twinblock functional appliance compared with an delayed treatment control in terms of:
1. Skeletal and dental improvement
2. Self esteem, psycho-social impact of malocclusion and oral health quality of life

Ethics approval required
Old ethics approval format

Ethics approval(s)
Multicentre Research Ethics Committee (MREC); 11/NW/0312

Study design
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
Orthodontic Myofunctional Braces, Skeletal / malocclusion Class II div (i), Sub speciality of dentistry

Interventions
The intervention is an orthodontic brace used to correct the small lower jaw and prominent upper teeth which is called a 'twinblock'. This brace has been in use for over 30 years and is used widely on growing children between 10.5 and 15 years old.

All children wear the brace for 18 months. The difference is when you have your treatment
Group 1: wears the brace straight away
Group 2: has to wait 18 months to become a little older

Intervention Type
Device

Primary outcome measure
1. Facial and dental movements
2. Study models plaster casts to measure tooth movements
3. X-ray to measure facial/jaw growth

Secondary outcome measures
1. Self esteem - Piers Harris 2002 questionnaire
2. Psychosocial impact OASIS (Mandall et al 200) validated questionnaire
3. Oral health quality of life questionnaire (Jokovic et al 2002)

Overall study start date
29/12/2011

Completion date
29/12/2017

Eligibility

Key inclusion criteria
1. Girls who are nearing their 11th birthday
2. Boys who are nearing their 12th birthday
3. Overjet (upper teeth prominence) of 7mm or more
4. Skeletal class II jaw pattern (a lower jaw which is set back)
5. White Caucasian children only
6. Written parent and child consent

Participant type(s)
Patient

Age group
Child

Lower age limit
10 Years

Upper age limit
11 Years

Sex
Both

Target number of participants
112 (56 in each group)

Key exclusion criteria
1. Girls older than 12.5 years
2. Boys older than 13.5 years
3. Cleft lip or palate or craniofacial syndrome
4. Lower jaw asymmetry
5. Muscular dystrophy
6. General health precludes treatment
7. Presence of medically diagnosed growth excess or deficiency
8. Not dentally fit - presence of tooth decay or gum disease
9. Previous orthodontic treatment

Date of first enrolment
29/12/2011

Date of final enrolment
01/12/2014

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Tameside Hospital NHS Foundation Trust
Greater Manchester
United Kingdom
OL6 9RW

Sponsor information

Organisation
Tameside Hospital NHS Foundation Trust (UK)

Sponsor details
c/o Dr Nicky Mandall
Fountain Street
Ashton-under-Lyne
Lancashire
Greater Manchester
England
United Kingdom

OL6 9RW
+44 (0)161 331 6383
John.goodenough@tgh.nhs.uk

Sponsor type
Hospital/treatment centre

Website
http://www.tamesidehospital.nhs.uk/

ROR
https://ror.org/04d713p41

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Tameside Hospital NHS Foundation Trust (UK)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date
01/12/2021

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available as there is no participant consent to share data

IPD sharing plan summary
Not expected to be made available