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A clinical trial to assess the effectiveness of miniplate surgical treatment to bring the upper jaw forwards in 11-14 years old children

Submission date
02/09/2014

Recruitment status
No longer recruiting

Registration date
19/09/2014

Overall study status
Completed

Last Edited
29/10/2024

Condition category
Oral Health

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

Plain English summary of protocol

Background and study aims
Children with a lower jaw protruding forward of the upper jaw have what is called a class III skeletal pattern. In some cases, it is caused by the upper jaw being set too far back. The treatment in such cases is to bring the upper jaw forward to correct the reverse bite. Patients are not usually offered corrective treatment until their general and facial growth is complete at around 17-18 years of age, at which point they may be offered orthognathic (jaw) surgery to correct the position of the jaw. The surgery involves a controlled break of the upper and lower jaw from inside the mouth which are then screwed into place to hold the jaws into their new position. There is an early treatment option, for children under the age of 10 that may prevent them from having to undergo the surgery when they are older. This means wearing reverse headgear, which brings the top jaw and teeth forwards over time and has a 70% success rate, but this option only works for children under the age of 10. There is, however, another option for 11-14 year olds. This is called Bone Anchored Maxillary Protection (BAMP). It involves places small metal plates (miniplates) from inside the mouth into the front part of the cheekbone next to the upper molars on each side. Further miniplates are positioned near the front of the lower jaw. Elastics are then attached from the upper to the lower plates, via hooks, to bring the upper jaw and teeth forwards and correct the class III skeletal pattern. At the moment, BAMP is not used routinely used in the UK. Here, we want to see how well it performs compared with a no treatment (control group) to see whether it reduces the need for orthognathic surgery at a later date.

Who can participate?
Children aged between 11-14, with a class III skeletal pattern and a reverse bite.

What does the study involve?
Participants are randomly allocated into one of two groups. Those in group 1 undergo BAMP surgery. Those in group 2 are given no treatment. The success of the treatment will be assessed according to how much the upper jaw moves to correct the reverse bite and whether orthognathic surgery is needed at a later date. All participants are followed up at 1 year and 3 years after the start of the trial to compare the outcomes for each group.

What are the possible benefits and risks of participating?
Possible benefits of BAMP include avoiding orthognathic surgery at a later date. The treatment is also considerably cheaper than orthognathic surgery and is a 30 minute daycase procedure rather than a treatment requiring a 3 day stay in hospital.

Where is the study run from?
The trial is multicentre with proposed sites: Tameside Hospital NHS Foundation Trust (Lead site), University Hospital of south Manchester (Wythenshawe Hospital), Bradford Royal Infirmary, Sheffield Dental Hospital, Newcastle Dental Hospital, Peterborough General Hospital, Southend Hospital, Kent and Canterbury Hospital (UK)

When is the study starting and how long is it expected to run for?
January 2015 to October 2022

Who is funding the study?
DB Orthodontics (UK)

Who is the main contact?
Dr Nicola Mandall
(see contact details below)

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

Integrated Research Application System (IRAS)
160532

Protocol serial number
Protocol version 1. 2/6/14, Tameside Hospital Reference: MC/2014/323, IRAS 160532

Study information

Scientific Title

A multicentre randomised clinical trial to investigate whether Bone Anchored Maxillary Protraction (BAMP) reduces the need for orthognathic (facial) surgery

Acronym
BAMP

Study objectives
Null hypothesis: There is no difference in the effectiveness of BAMP versus no treatment /control group in terms of: need for later orthognathic facial surgery, skeletal forward movement of the maxilla (upper jaw), correction of reverse overjet, facial profile improvement.

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES committee North West Greater Manchester Central, 19/02/2015, ref: 15/NW/0022

Study design
Multicentre randomized controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Oral and maxillofacial surgery and orthodontics

Interventions
Group 1: BAMP surgery
Group 2: Control/no treatment

BAMP consists of small metal plates that are inserted from inside the mouth into the front part of the cheekbone bone next to the upper molars on each side. Further miniplates are positioned into the bone down in the lower canine region near the front of the lower jaw. Elastics are then attached from the upper to the lower plates, via hooks, to bring the upper jaw and teeth forwards and correct the class III skeletal pattern. The miniplates are placed and later removed as a daycase general anaesthetic procedure and the patient wears the elastics for around 6-8 months.

Intervention Type
Procedure/Surgery

Primary outcome(s)
1. Need for orthognathic surgery later
2. Amount of forward movement of the maxilla (upper jaw) to correct the reverse bite
3. Reverse overjet (bite) correction

Need for orthognathic surgery will be measured through consultant clinical panel consensus method using patient records. Forward movement of the maxilla will be measured from lateral

cephalogram radiographs. Reverse overbite correction will be measured from plaster study models of the patients teeth using a metal ruler. The outcomes will be measured at baseline, 1 and 3 years follow-up.

Key secondary outcome(s))
1. Facial aesthetic improvement
2. Patient discomfort log following surgery
3. Operating time for the BAMP surgery
4. BAMP - post operative infection rates and plate failure rates

Facial aesthetic improvement will be measured using panel consensus of facial profiles photographs. Patient discomfort log will be recorded on a 7 point Likert scale with 1 = no pain at all to 7 severe pain. Operating time for BAMP surgery will be recorded from the theatre time log. Post operative infection rates and plate failure rates will be recorded from the patient notes. The outcomes will be measured at baseline, 1 and 3 years follow-up.

Completion date
01/10/2022

Eligibility

Key inclusion criteria
1. Age 11-14 years old
2. Class III skeletal pattern with reverse bite of at least 1mm
3. Dentally fit
4. Written consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Child

Lower age limit
11 years

Upper age limit
14 years

Sex
All

Total final enrolment
57

Key exclusion criteria

1. Cleft lip and or palate or craniofacial syndrome
2. Reverse bite greater than 6mm
3. Lower jaw asymmetric
4. Muscular dystrophy (weakness)
5. Patient smokes

Date of first enrolment
06/07/2015

Date of final enrolment
01/10/2019

Locations

Countries of recruitment
United Kingdom

England

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

Sponsor information

Organisation
Tameside Hospital NHS Foundation Trust (UK)

ROR
https://ror.org/04d713p41

Funder(s)

Funder type
Industry

Funder Name
DB Orthodontics (UK)

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are not expected to be made available. The data will be held at Tameside and Glossop Integrated Care NHS Foundation Trust and copied to the R+D dept for electronic archiving.

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		06/06/2024	29/10/2024	Yes	No
HRA research summary			28/06/2023	No	No