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An investigation of treating patients with conventional and skeletal anchored protraction headgear

Submission date
02/04/2020

Recruitment status
No longer recruiting

Registration date
07/04/2020

Overall study status
Completed

Last Edited
15/05/2023

Condition category
Musculoskeletal Diseases

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

Plain English summary of protocol

Background and study aims
Facemask therapy has been available for many years and researchers have tried to modify it in a more beneficial way. However, many studies showed controversies in results and never agreed on the optimum wearing time and the optimum force needed to induce maximum skeletal changes. Later in 2000, a new method was introduced using the ALTRAMEC technique which makes the maxilla (upper jaw) more mobile and malleable to be pushed forward. The latter approach was showed to have benefits over the conventional method but so far there is a lack of evidence of whether a skeletal anchored appliance will induce skeletal anchorage in comparison to the dental borne appliance. The aim of this study is to assess the compliance rate, the skeletal and dental effect, and the effect on patients' quality of life of a skeletal anchored appliance.

Who can participate?
Children aged 8-11 who are Skeletal Class III

What does the study involve?
Participants are randomly allocated to one of two groups. The control group receive a conventional facemask while the study group receive a skeletal anchored device. The skeletal anchored device includes placing two mini-implants in the palate of the patients then fabricating an orthodontic appliance that will set over them.

What are the possible benefits and risks of participating?
Possible benefits include improved quality of life, skeletal and dental relationships, and self-esteem, and reduced risk for orthognathic surgery. There are no risks since all patients are receiving treatment.

Where is the study run from?
University of Malta (Malta)

When is the study starting and how long is it expected to run for?
December 2019 to December 2022

Who is funding the study?
University of Malta (Malta)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
HEC04/19

Study information

Scientific Title
Treatment outcomes of protraction headgear in pre-pubertal patients

Study objectives
The hypothesis is based on whether the skeletal anchored facemask is more effective in comparison to conventional facemask group.

Ethics approval required

Old ethics approval format

Ethics approval(s)
Approved 29/11/2019, Ministry of Health and Research in Malta (Directorate for Health Information & Research, 95, Guardamangia Hill, Pieta' PTA 1313, Malta; +356 (0)25599000; hec@gov.mt), ref: HEC04/19

Study design
Randomized clinical 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 to request a participant information sheet

Health condition(s) or problem(s) studied
Class III malocclusion

Interventions
Patients will be recruited from the Orthodontic Department in the Department of Dental Surgery at Mater Dei Hospital, Malta.
Subsequently, each name will have a correspondent code for the purpose of anonymization. The design will follow CONSORT guidelines ensuring that a systematic methodology is followed.

Routine orthodontic treatment protocols will be followed thus, patients' pre-treatment and post-treatment ''Lateral Cephalogram'' radiographs will be evaluated to assess the skeletal and dental effects of the appliances via assessing specific landmarks. Following the cessation of the treatment, a period of 2 years follow up will assess the stability of facemask therapy prior to the commence of fixed orthodontic appliance treatment.

The lateral cephalogram will be analysed using specific angular and linear measurements. Lateral cephalograms will be traced by the same investigator to avoid inter-examiner error, the same lateral cephalograms will be traced again to establish intra-examiner reliability. Furthermore, the inter-examiner reliability test will be conducted to reduce any possible biases. Lateral cephalograms will be analysed by McNamara analysis to assess the angular and linear changes.

The same lateral cephalogram images will be used to assess patients' skeletal maturity using the CVM staging method. In addition, growth charts to assess the change in patients' height velocity

will also be used. Using two indices to assess the patients' physical maturity will enhance the reliability of all patients being in the pre-pubertal stages. All patients should be in CS1 and CS2 when facemask treatment will take place.

Patients in the hybrid HYRAX facemask group will have a CBCT taken pre-treatment and post-treatment, as outlined by European radiation guidelines. The guideline states when placement of implant near a vital structure a CBCT should be taken to ensure avoidance of any harm. Since in this study two mini-implants will be placed in the palate which is close to the canine position, CBCT is necessary to guide the exact placement of the mini-implant. On the day of mini-implant removal, a small field of view CBCT will be needed to ensure no adverse effect has taken place during treatment. The CBCT will be a small field of view image which will show only the maxilla and palate.

All patients will be given a consent form and an explanatory letter about the research in English and Maltese. Following consent, patients' names will be blinded by coding. These codes will be randomised through Microsoft Excel (Microsoft Corporation, USA) to sort the patients into two groups. Routine orthodontic records, i.e. other clinically necessary radiographs, photographs and study models will be taken.

The HYRAX will be anchored skeletally by two (9 mm X 2 mm) mini-implants at the paramedian region behind the 3rd palatal rugae, which is the most stable landmark of insertion due to good bone quality at that side. Local anaesthesia will be given followed by insertion of the mini-implant with a motor rotary handpiece. Caps will be placed to cover the mini-implant then an impression will be taken, then an analogue will be placed in the impression to be poured in the dental laboratory. The appliance will be fitted in the mouth following laboratory fabrication. The conventional facemask group will follow a routine impression protocol to fabricate a rapid maxillary expansion appliance which will be cemented to the teeth. Both groups will be fitted with a Petit facemask with elastics attached at the molar-premolar region above the occlusal plane (as close as possible to the maxillary centre of resistance). The facemask will be worn for 15 hours with a force of approximately 700-800 g per side.

Furthermore, patients' compliance will be assessed via the use of a sensor implanted in the facemask pad. The ''Theramon'' is a heat detector sensor which will detect any change in the temperature, e.g. the change in temperature from contact with a patient's skin. Theramon sensor will be concealed underneath the facemask forehead pad without informing the patients. The clinician will ask the patients to use the appliance at least 15 hours per day and every month the investigator will record the sensor readings. During the review appointment, the sensor will be scanned using a wireless reader attached to a computer device which will report how many hours the patient wore the appliance. Blinding the patients to the sensor will give unbiased results and allow the relation of wear compliance and facemask effects. In addition, patients will be asked to score how many hours they have worn the appliance per day via a ready-made time table.

Intervention Type
Device

Pharmaceutical study type(s)
Not Applicable

Phase
Phase I

Drug/device/biological/vaccine name(s)
HYRAX skeletal anchored facemask

Primary outcome measure
Compliance rate of wearing protraction headgear assessed using a compliance sensor (Theramon) concealed in the facemask pad over a period of 9 months: T1= 1 month, T2=2 months, T3, T4, T5, T6, T7, T8, and T9.

Secondary outcome measures
1. Skeletal and dental-related outcome measured with a cephalometric x-ray at T0 before treatment and T1 after treatment
2. Quality of life assessed using the Child Perception Questionnaire (CPQ8-11) before study start T0 (baseline) then on monthly for 9 months (T1 to T9)

Overall study start date
01/12/2019

Completion date
10/12/2022

Eligibility

Key inclusion criteria
1. Skeletal Class III
2. Healthy children with no systemic diseases
3. Age between 8-12 years
4. Co-operative children
5. Good oral hygiene
6. True skeletal III without shift
7. All dentition present
8. Healthy periodontium
9. No previous orthodontic treatment

Participant type(s)
Patient

Age group
Child

Lower age limit
8 Years

Upper age limit
12 Years

Sex
Both

Target number of participants
32

Total final enrolment
35

Key exclusion criteria
1. Skeletal Class II or I
2. Children with systemic diseases.
3. Below 8 years and above 12 years
4. Apprehensive children
5. Poor oral hygiene
6. Mandibular shift (Pseudo-Class III)
7. Hypodontia
8. Periodontal disease
9. Previous history of orthodontic treatment including removable appliance

Date of first enrolment
01/01/2020

Date of final enrolment
01/01/2021

Locations

Countries of recruitment
Malta

Study participating centre
University of Malta Teaching clinics
Medical School
Mater Dei Hospital
Msida
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Sponsor information

Organisation
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University/education

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Funder(s)

Funder type
University/education

Funder Name
University of Malta

Results and Publications

Publication and dissemination plan
Will be published in a peer-reviewed journal.

Intention to publish date
01/01/2023

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication. The raw data will be secured in a closed cabinet at the faculty of dental surgery at the University of Malta. Only the main investigator has access to that raw data and following data entry and analysis all this raw data will be discarded via a mechanical means such as a shredder.

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	11/05/2023	15/05/2023	Yes	No