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Making skeletal class III malocclusion treatment more effective by using a facemask and a modified skeletal expander

Submission date 20/01/2023	**Recruitment status** No longer recruiting	[X] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 24/01/2023	**Overall study status** Completed	
Last Edited 30/01/2024	**Condition category** Oral Health	

Plain English summary of protocol

Background and study aims
Skeletal class III malocclusion is a condition where the upper jaw is smaller than the lower jaw. This malocclusion is caused by a discrepancy in the size, shape, or position of the maxilla (upper jaw) and mandible (lower jaw) bones, and can lead to difficulty with biting and chewing, as well as visual appearance concerns. Rapid maxillary expansion and facial mask therapy is the most common treatment method for skeletal class III malocclusion in growing patients. Along with the effectiveness of this method, it has been associated with many side effects such as inclination movement of supporting teeth, and loss of height and thickness of the buccal bone. This trial aims to evaluate the effectiveness of buccal and labial pads in skeletal class III malocclusion treatment using a face mask appliance combined with rapid maxillary expansion. The purpose of buccal and labial acrylic pads is to remove the pressure applied to the maxillary from lips and cheeks and apply periosteal traction to stimulate the formation of the buccal bone.

Who can participate?
Children aged 7-10 years old with skeletal class III malocclusion

What does the study involve?
Patients will be randomly allocated into two groups:
Arm 1:
Experimental group: Each Patient in this group will be treated with a modified skeletal expander and face mask appliance.
*The expander used in this group was modified by adding buccal and labial acrylic pads.
Arm 2:
Controlled group: Each Patient in this group will be treated with a traditional skeletal expander and face mask appliance.

What are the possible benefits and risks of participating?
Using this modified device may improve the efficiency of skeletal Class III Malocclusion treatment. There are no expected risks of participating.

Where is the study run from?
Damascus University (Syria)

When is the study starting and how long is it expected to run for?
April 2022 to June 2024

Who is funding the study?
Damascus University (Syria)

Who is the main contact?
Dr Ahmad Alhamwi, ahmad.hamwi.1996@gmail.com

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
2620

Study information

Scientific Title
Effectiveness of buccal and labial pads addition in improving the efficiency of skeletal class III malocclusion treatment using face mask appliance combined with rapid maxillary expansion: a randomized controlled clinical trial

Study objectives
1. Using a modified skeletal expander improves the efficiency of treatment in the sagittal plane.
2. Using a modified skeletal expander improves the efficiency of treatment in the transverse plane.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 09/05/2022, Scientific research and postgraduate studies council of Damascus University (Damascus, Syria 80789; +963 (0)993303359; ap.srd@damascusuniversity.edu.sy), ref: 2620

Study design
Interventional single-center single-blinded randomized parallel-group controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Dental clinic

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet.

Health condition(s) or problem(s) studied
Skeletal class III and maxillary transverse deficiency.

Interventions
Patients will be randomly allocated into two groups using Microsoft® Excel electronic randomization:
Arm 1:
Experimental group: Each Patient in this group will be treated with a modified skeletal expander and face mask appliance. The treatment will begin with the placement of bonded expander on the upper arch. The patients will be instructed to activate the expander twice a day until the desired transverse width is achieved (two weeks).
The patients will be given facemasks immediately after the expansion ends, and will be instructed to wear the appliance for a minimum of 14 hours per day. All patients will be treated at least to a positive, over-corrected dental overjet before discontinuing treatment with the facemask appliance.
*The expander used in this group was modified by adding buccal and labial acrylic pads.
Arm 2:
Control group: Each Patient in this group will be treated with a traditional bonded skeletal expander and face mask appliance. The treatment protocol used in this group is the same as described in the experimental group.

Intervention Type
Device

Pharmaceutical study type(s)
Not Applicable

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Modified skeletal expander and face mask appliance with buccal and labial acrylic pads, traditional skeletal expander and face mask appliance

Primary outcome measure
1. Sagittal and vertical skeletal changes before and after treatment will be assessed using cone-beam computed tomography-generated cephalograms.
2. Dentoalveolar changes including:
2.1. Upper incisor angle changes.
2.2. The permanent maxillary first molar inclination changes.
2.3. Height and thickness of alveolar bone.
Dentoalveolar changes before and after treatment will be assessed using cone-beam computed tomography.

Secondary outcome measures

1. Soft tissue changes before and after treatment will be assessed using profile photography.
2. Levels of pain and discomfort measured using a questionnaire given to the patients.

Overall study start date
01/04/2022

Completion date
20/06/2024

Eligibility

Key inclusion criteria
1. Skeletal class III caused by maxillary deficiency with or without mandibular prognathism.
2. Maxillary transverse deficiency.
3. Patients with normal or horizontal growth patterns.
4. Patients in early mixed dentition (7-10 years old).

Participant type(s)
Patient

Age group
Child

Lower age limit
7 Years

Upper age limit
10 Years

Sex
Both

Target number of participants
40

Key exclusion criteria
1. Patients with syndromes or craniofacial abnormalities.
2. Patients with vertical growth patterns.
3. Poor oral hygiene.
4. Previous orthodontic treatment.

Date of first enrolment
01/04/2023

Date of final enrolment
01/12/2023

Locations

Countries of recruitment
Syria

Study participating centre
Damascus University
Department of orthodontics
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Sponsor information

Organisation
Damascus University

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Sponsor type
University/education

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Funder(s)

Funder type
University/education

Funder Name
Damascus University

Alternative Name(s)
University of Damascus, , DU

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
Syria

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal.

Intention to publish date
30/01/2025

Individual participant data (IPD) sharing plan
The datasets generated and analyzed during the current study during this study will be included in the subsequent results publication.

IPD sharing plan summary
Published as a supplement to the results publication