

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

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<b>Registration date</b> 24/01/2023	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 30/01/2024	<b>Condition category</b> Oral Health	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

## 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

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## Additional identifiers

### Clinical Trials Information System (CTIS)

Nil known

### ClinicalTrials.gov (NCT)

Nil known

### Protocol serial number

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

### Study type(s)

Treatment

### 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

## **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(s)**

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.

## **Key secondary outcome(s)**

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.

## **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

**Healthy volunteers allowed**

No

**Age group**

Child

**Lower age limit**

7 years

**Upper age limit**

10 years

**Sex**

All

**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

Faculty of Dentistry

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Damascus

Syria

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**Sponsor information**

**Organisation**

Damascus University

**ROR**

<https://ror.org/03m098d13>

**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****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