

# Patient-reported outcomes associated with face mask and rapid palatal expansion

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<b>Registration date</b> 01/07/2025	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 07/07/2025	<b>Condition category</b> Oral Health	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

Rapid maxillary expansion and facemask (RME/FM) are commonly used together for the orthopaedic treatment of growing Class III patients, whose lower teeth and jaw project further forward than the upper teeth and jaws. There are no studies in the medical literature that have examined patient-reported outcomes associated with treatment using RME/FM. This study aims to evaluate the patient-reported outcomes associated with the facemask and rapid palatal expansion.

### Who can participate?

Patients in early mixed dentition (when both baby and permanent teeth are present in the mouth, 7-10 years old)

### What does the study involve?

A standardised questionnaire was used to assess pain and functional impairment levels during the first 6 months of RME/FM treatment.

### What are the possible benefits and risks of participating?

The study will provide information on the patient-reported outcomes associated with the facemask and rapid palatal expansion.

### Where is the study run from?

Damascus University (Syria)

### When is the study starting and how long is it expected to run for?

May 2022 to February 2025

### Who is funding the study?

Damascus University (Syria)

### Who is the main contact?

Dr Ahmad Alhamwi, [ahmad.hamwi.1996@gmail.com](mailto:ahmad.hamwi.1996@gmail.com)

# Contact information

## Type(s)

Scientific, Principal Investigator

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# Additional identifiers

## EudraCT/CTIS number

Nil known

## IRAS number

## ClinicalTrials.gov number

Nil known

## **Secondary identifying numbers**

Nil known

# **Study information**

## **Scientific Title**

Patient-reported outcomes of orthodontic treatment for skeletal Class III malocclusion using face mask with rapid palatal expansion: a prospective clinical trial

## **Study objectives**

Using a face mask and rapid maxillary expansion (FM+RME) affects the patient-reported outcomes.

## **Ethics approval required**

Ethics approval required

## **Ethics approval(s)**

Approved 17/05/2022, Scientific research and postgraduate studies council of Damascus University (Damascus University, Damascus, 80789, Syria; +963 (0)993303359; ap.srd@damascusuniversity.edu.sy), ref: 2622

## **Study design**

Prospective clinical trial

## **Primary study design**

Interventional

## **Secondary study design**

Non randomised study

## **Study setting(s)**

University/medical school/dental school

## **Study type(s)**

Quality of life

## **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**

Skeletal class III malocclusion

## **Interventions**

The treatment will begin with the placement of a bonded expander on the upper arch. The patients will be instructed to activate the expander once a day until the desired transverse width is achieved.

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.

**Intervention Type**

Device

**Pharmaceutical study type(s)**

Not Applicable

**Phase**

Not Applicable

**Drug/device/biological/vaccine name(s)**

Facemask + RME

**Primary outcome measure**

1. Pain
2. Pressure
3. Difficulty in swallowing
4. Difficulty in speaking
5. Lack of confidence

All outcomes were measured using the numeric rating scale (NRS) at 24 hours, 1 week, 2 weeks after activation of RME, and after 1 week, 1 month, 3 months and 6 months after facemask application. Participants were asked to rate their experience for each variable between 0 (least severity) and 10 (maximum severity)

**Secondary outcome measures**

There are no secondary outcome measures

**Overall study start date**

17/05/2022

**Completion date**

05/02/2025

## Eligibility

**Key inclusion criteria**

1. Skeletal class III caused by maxillary deficiency with or without mandibular prognathism
2. Patients with normal or horizontal growth patterns
3. 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**

19

**Total final enrolment**

19

**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**

20/05/2023

**Date of final enrolment**

07/01/2024

**Locations****Countries of recruitment**

Syria

**Study participating centre**

**Damascus University**

Department of Orthodontics

Faculty of Dentistry

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**Sponsor information****Organisation**

Damascus University

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**Sponsor type**

University/education

**Website**

<http://damasuniv.edu.sy>

**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****Publication and dissemination plan**

Planned publication in a high-impact peer-reviewed journal.

**Intention to publish date**

01/09/2025

**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