

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

Submission date 29/06/2025	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 01/07/2025	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 07/07/2025	Condition category 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

Contact information

Type(s)

Scientific, Principal investigator

Contact name

Dr Ahmad Alhamwi

ORCID ID

<https://orcid.org/0000-0002-1919-033X>

Contact details

Department of Orthodontics
Faculty of Dentistry
Damascus University
Al-Mazzeah Street
Damascus
Syria
0004
+963 (0)993373851
ahmad.hamwi.1996@gmail.com

Type(s)

Public, Scientific

Contact name

Prof Ahmad Burhan

ORCID ID

<https://orcid.org/0000-0002-0727-2653>

Contact details

Department of Orthodontics
Faculty of Dentistry
Damascus University
Al-Mazzeah Street
Damascus
Syria
0004
+963 (0)944302075
dr.burhan-a@hotmail.com

Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

Protocol serial number

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

Study type(s)

Quality of life

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

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Facemask + RME

Primary outcome(s)

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)

Key secondary outcome(s)

There are no secondary outcome measures

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

Healthy volunteers allowed

No

Age group

Child

Lower age limit

7 years

Upper age limit

10 years

Sex

All

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

Al-Mazzeah Street

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