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

Submission date	Recruitment status	[_] Prospectively registered
29/06/2025	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
01/07/2025	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
07/07/2025	Oral Health	[X] 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?
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Contact information

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Scientific, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
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
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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