

Muscular tension effect on the dental movement during the maxillary dental arch expansion - a randomized clinical controlled trial

Submission date 24/11/2023	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 27/11/2023	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 22/01/2026	Condition category Oral Health	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Maxillary compression is a condition where the upper jaw has a misalignment, often leading to lateral crossbites. This can affect the dental arch in different ways. In orthodontic treatment for children, expanding the upper jaw is often necessary. This study aims to explore the treatment of maxillary compression in children using both basal and traditional removable plates.

Who can participate?

Children aged between 8 and 12 years old who require treatment for dentoalveolar maxillary compression

What does the study involve?

The patients will be randomly divided into two equal groups and a Master's student at the Orthodontics Department at Damascus University will apply the devices:

The first group (control) will be treated with a traditional expansion plate. The second group (experimental) will be treated with a basal expansion plate. The duration of treatment is 6 months.

What are the possible benefits and risks of participating?

The expected benefit is getting skeletal expansion without risks.

Where is the study run from?

Damascus University (Syria)

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

November 2021 to October 2023

Who is funding the study?

Damascus University (Syria)

Who is the main contact?

Suzan Ibraheem, Suzan7Ibraheem@damascusuniversity.edu.sy (Syria)

Contact information

Type(s)

Public, Scientific, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

Funder ref: 501100020595

Study information

Scientific Title

Slow maxillary expansion

Study objectives

There is no significant difference in skeletal and dentoalveolar changes between basal removable plate and traditional removable plate

Ethics approval required

Ethics approval not required

Ethics approval(s)

Ethics approval was not required because the devices used are a mixture of previously used devices. Ref: No. /459/ dated 29/03/2022.

Study design

Randomized controlled trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Treatment of maxillary compression in children

Interventions

The aim of this study was to investigate the effectiveness of a basal expansion plate compared to a traditional expansion plate in the treatment of maxillary compression.

Simple randomization will be used by asking each participating patient to pick a piece of paper from an opaque plastic box, that contains 40 papers, half of them marked with the letter C, i.e., the control group (the control group treated with a traditional removable plate), and half are marked with the letter E, i.e., the experimental group (the experimental group treated with a basal removable plate). The duration of treatment is 6 months

The intervention provider was a Master's Degree student at the Department of Orthodontics. The modes of delivery were face-to-face and it was provided individually.

All interventions were at the Department of Orthodontics and Dentofacial Orthopedics, Faculty of Dentistry -Damascus University.

Intervention Type

Device

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Traditional removable maxillary compression plate, basal removable maxillary compression plate

Primary outcome(s)

Skeletal and dentoalveolar changes measured using frontal and lateral cephalometric photos and cast models at the beginning of treatment and after 6 months

Key secondary outcome(s))

Tension, pressure, pain, lack of confidence, swallowing difficulties and speech difficulties measured using a Numerical Rating Scale (NRS) after one week, one month, 3 months and 6 months

Completion date

17/10/2023

Eligibility

Key inclusion criteria

1. Patients in the mixed dentition
2. Chronological age between 8 and 12 years old
3. Dentoalveolar maxillary constriction
4. Dental and skeletal class I and II malocclusion
5. The presence of upper first permanent molars
6. No systematic diseases
7. Good oral health

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Child

Lower age limit

8 years

Upper age limit

12 years

Sex

All

Total final enrolment

42

Key exclusion criteria

1. Constriction in the anterior region
2. Presence of general diseases, syndromes, or cleft lip and palate
3. Patients with previous orthodontic treatment

Date of first enrolment

15/11/2022

Date of final enrolment

15/04/2023

Locations

Countries of recruitment

Syria

Study participating centre

Damascus University

Damascus-Al - Mazzeh

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

IPD sharing plan summary

Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		21/01/2026	22/01/2026	Yes	No
Participant information sheet			27/11/2023	No	Yes