ISRCTN69542858 https://doi.org/10.1186/ISRCTN69542858

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	[_] Prospectively registered [_] Protocol
Registration date 27/11/2023	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 20/09/2024	**Condition category** Oral Health	[_] Individual participant data [X] Record updated in last year

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

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Funder ref: 501100020595

Study information

Scientific Title
Slow maxillary expansion

Study objectives
There is no significant difference in skeletal and dentoalveolar changes betweem 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

Secondary study design
Randomised controlled trial

Study setting(s)
University/medical school/dental school

Study type(s)
Treatment

Participant information sheet
See study outputs table

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

Pharmaceutical study type(s)
Not Applicable

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Traditional removable maxillary compression plate, basal removable maxillary compression plate

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

Secondary outcome measures
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

Overall study start date
15/11/2021

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

Age group
Child

Lower age limit
8 Years

Upper age limit
12 Years

Sex
Both

Target number of participants
Two groups, each group contain 20 patients

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
-

Sponsor information

Organisation
Damascus University

Sponsor details
Albaramkeh
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Sponsor type
University/education

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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
15/11/2024

Individual participant data (IPD) sharing plan
The data-sharing plans for the current study are unknown and will be made available at a later date

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?
Participant information sheet			27/11/2023	No	Yes