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Comparing the impact of slow and rapid maxillary expansion on the upper airway

Submission date
27/10/2023

Recruitment status
No longer recruiting

Registration date
09/11/2023

Overall study status
Completed

Last Edited
09/11/2023

Condition category
Oral Health

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Transverse maxillary deficiency is a condition where the upper jaw (maxilla) is narrower than it should be. Is is commonly observed in daily clinical practice, often accompanied by a narrowing of the nasal airway. Several methods have been used to expand the upper maxilla and treat this condition, including slow maxillary expansion with light force and rapid maxillary expansion. Several studies have highlighted the role of rapid maxillary expansion in increasing the size of the nasal cavity and improving respiratory airway volume. However, the role of slow maxillary expansion still requires further investigation and study to determine its effectiveness in achieving similar outcomes. Additional research is needed to explore the effects of slow maxillary expansion on the nasal airway and respiratory function.

Who can participate?
Patients aged 8-11 years with transverse maxillary deficiency

What does the study involve?
Patients are randomly allocated to slow maxillary expansion or rapid maxillary expansion. In the slow expansion group, the Hyrax expander is applied and activated twice a week. In the rapid expansion group, the Hyrax expander is applied and activated twice a day.

What are the possible benefits and risks of participating?
The benefits include determining whether slow maxillary expansion has a similar effect on increasing respiratory airway volume as rapid maxillary expansion, which has more side effects. The potential risks are discomfort or pain during the process, gingival (gum) irritation, temporary speech changes, and root resorption.

Where is the study run from?
Damascus University (Syria)

When is the study starting and how long is it expected to run for?
June 2022 to May 2024

Who is funding the study?
Damascus University (Syria)

Who is the main contact?
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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
2904

Study information

Scientific Title
In patients with maxillary transverse deficiency, what are the effects of slow maxillary expansion compared to rapid maxillary expansion on upper airways as measured by cone beam computed tomography?

Study objectives
Null hypothesis:
There is no significant difference in the effects on upper airways, as measured by cone beam computed tomography (CBCT), between slow maxillary expansion and rapid maxillary expansion in patients with maxillary transverse deficiency.

Alternative hypothesis:
Slow maxillary expansion has different effects on upper airways compared to rapid maxillary expansion in patients with maxillary transverse deficiency, as measured by CBCT.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 06/06/2022, Scientific research and postgraduate studies council of Damascus University (-, Damascus, 80789, Syria; +963 (0)993303359; ap.srd@damascusuniversity.edu.sy), ref: 2904

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

Health condition(s) or problem(s) studied
Transverse maxillary deficiency

Interventions
Patients are randomly selected using a simple manual method, where each patient was asked to draw an envelope containing either Model 1 or Model 2, and then write their name on the envelope they selected, keeping it sealed and hidden from the researcher to ensure unbiased distribution. Based on this, the distribution was as follows:
In 1: Slow maxillary expansion group.
In 2: Rapid maxillary expansion group.
In the slow expansion group, the Hyrax expander is applied, and the expander is activated twice a week.
In the rapid expansion group, the Hyrax expander is applied, and the expander is activated twice a day.

The treatment duration is 6 months with no follow-up.

Intervention Type
Procedure/Surgery

Primary outcome measure

Changes in the upper airways measured using CBCT at T0 before applying device and at T1 after applying the device for 6 months

Secondary outcome measures
The following distances were measured perpendicular to CorPL and SrPL at T0 (before applying the device) and T1 (after applying the device for 6 months)

Skeletal measurements
1. Anterior maxillary expansion: RPyP-LPyP
2. Posterior maxillary expansion: RPaFoP-LPaFoP
3. Pterygoid expansion: PtR-PtL

Dentoalveolar measurements :
1. Molar expansion: at the molar cusp, CR-CL; at palatal root apex, AR-AL
2. Molar tipping: the difference between (AR-AL) and (CR-CL)

Abbreviations:
RPyP: Right piriform point. The most lateral and caudal point of the nasal piriform aperture at the boundary with the palatal cortex. This landmark was primarily identified in coronal CT slices passing through the anterior edge of the nasopalatine foramen within the palatal cortex.
LPyP: Analogue to RPyP, left side.
RPaFoP: Right palatine foramen point. The most posterior point of the right greater palatine foramen in the maxilla within the palatal cortex.
LPaFoP: Analogue to RPaFOPr, left side.
PtR. Pterygoideous right. The most caudal point of the apex of the right pterygoid process of the sphenoid.
PtL. Pterygoideous left. Analogue to PtR, left side.
CR: Cuspid right. Mesio-palatal cusp tip of the right maxillary first molar.
CL: Cuspid left. Mesio-palatal cusp tip of the left maxillary first molar.
AR: Apex right. The apex of the palatal root of the right maxillary first molar.
AL: Apex left. The apex of the palatal root of the left maxillary first molar.
SrPL: Sagittal reference plane: The sagittal CT slice passing through the middle point of the segment OVpR-OVpL
COrPL: Coronal reference plane: The plane passing through OVpR-OVpL the oval point right and left (OVPr/OVPl)

Overall study start date
01/06/2022

Completion date
15/05/2024

Eligibility

Key inclusion criteria
1. Patients aged 8-11 years
2. Maxillary transverse constriction

Participant type(s)
Patient

Age group
Child

Lower age limit
8 Years

Upper age limit
11 Years

Sex
Both

Target number of participants
38

Key exclusion criteria
1. Patients with systemic diseases or craniofacial syndromes
2. Patients with poor oral health
3. Patients with dental crossbite

Date of first enrolment
18/07/2022

Date of final enrolment
15/10/2023

Locations

Countries of recruitment
Syria

Study participating centre
Damascus University
Syria
80789

Sponsor information

Organisation
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University/education

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ROR
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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
31/05/2024

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