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How to predict the success of rapid maxillary expansion

Submission date	Recruitment status	[ ] Prospectively registered
21/10/2023	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
25/10/2023	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
04/06/2025	Oral Health	

Plain English summary of protocol

Background and study aims
Rapid maxillary expansion (RME) is a common orthodontic treatment to correct transverse maxillary deficiency, where the upper jaw (maxilla) is narrower than it should be. Transverse discrepancies should be treated as soon as possible. There is still debate about what age the RME procedure would be ineffective and the only solution would be surgical-assisted RME (SARME). On the other hand, a preference for surgery in a case that could be treated without surgical assistance would make the patient suffer from an unnecessary operation which is invasive, costly, and involves surgical risks. This study aims to evaluate the indicators that predict the success of RME using cone beam CT (CBCT) scans.

Who can participate?
Patients aged 14-18 years with transverse maxillary deficiency

What does the study involve?
All participants undergo a CBCT scan before they undergo RME. According to a scan taken 4 days after the beginning of the RME procedure, patients are allocated into two groups: successful RME and failed RME. Five CBCT variables are evaluated to predict the success of RME.

What are the possible benefits and risks of participating?
All participants are made aware of the risks of the RME procedure. The risks include mucosal ulceration or necrosis, accentuated buccal tooth tipping, gingival recession and severe pain around the posterior teeth. Patients who had a successful RME continue their treatment as planned while patients in the failed RME group will complete the procedure by surgical-assisted rapid maxillary expansion (SARME).

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 June 2024

Who is funding the study?
Damascus University (Syria)

Who is the main contact?
Dr Mahmood Aleesh, mahmood.aleesh@damascusuniversity.edu.sy

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
3215

Study information

Scientific Title
Evaluation of indicators which predict the success of rapid maxillary expansion using cone beam computed tomography

Study objectives
Null hypothesis: There are no statistically significant differences in the degree of maturity of the median palatine suture on the cone beam computed tomography (CBCT) image between the group in which expansion was determined and the group in which it failed.

Alternative hypothesis: There are statistically significant differences in the degree of maturity of the median palatine suture on the CBCT image between the group that performed rapid maxillary expansion and the group that failed.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 04/07/2022, Scientific research and postgraduate studies council of Damascus University (Damascus, Syria, Damascus, 80789, Syria; +963 (0)993303359; ap.srd@damascusuniversity.edu.sy), ref: 3215

Study design
Prospective clinical trial

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Dental clinic

Study type(s)
Efficacy

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Skeletal cross bite

Interventions
The sample frame has been obtained by checking patients who came into the orthodontic department at Damascus University and got diagnosed with posterior skeletal crossbite, between the ages of 14-18 years. All patients who agreed to be a part of the research were asked to take a CBCT full skull radiograph before they undergo a rapid maxillary expansion (RME).

According to the occlusal radiograph taken 4 days after the beginning of the RME procedure which indicates the response of the midpalatal suture, patients were allocated into two groups according to expansion success:

Group 1: successful (S-RME)
Group 2: failed (F-RME)

Intervention Type
Procedure/Surgery

Primary outcome measure
Success of skeletal rapid maxillary expansion, measured by the following indicators using CBCT at a single timepoint:
1. Midpalatal Suture Maturation (MSM)

2. The length and thickness of the midpalatal suture
3. Midpalatal Suture Desity (MSD)
4. Cervical Vertebral Maturation (CVM)
5. The position of the upper jaw in the vertical plane based on the points anterior nasal spine (ANS) and posterior nasal spine (PNS)

Secondary outcome measures
There are no secondary outcome measures

Overall study start date
01/06/2022

Completion date
05/06/2024

Eligibility

Key inclusion criteria
1. Patients in the permanent occlusion stage aged between 14-18 years
2. Transverse maxillary deficiency (posterior skeletal crossbite)
3. No tooth loss
4. Good oral health

Participant type(s)
Patient

Age group
Child

Lower age limit
14 Years

Upper age limit
18 Years

Sex
Both

Target number of participants
40

Total final enrolment
46

Key exclusion criteria
1. Dental posterior crossbite
2. previous orthodontic treatment
3. The presence of extensive metal restorations in the teeth
4. The presence of periodontal diseases
5. The presence of cleft palate

Date of first enrolment
04/04/2023

Date of final enrolment
10/02/2024

Locations

Countries of recruitment
Syria

Study participating centre
Damascus University
Department of Orthodontics
Faculty of Dentistry
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Sponsor information

Organisation
Damascus University

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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
12/08/2024

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		02/06/2025	04/06/2025	Yes	No