

How to predict the success of rapid maxillary expansion

Submission date 21/10/2023	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 25/10/2023	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 04/06/2025	Condition category Oral Health	<input type="checkbox"/> Individual participant data

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

Protocol serial number

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

Study type(s)

Efficacy

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(s)

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 Density (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)

Key secondary outcome(s)

There are no secondary outcome measures

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

Healthy volunteers allowed

No

Age group

Child

Lower age limit

14 years

Upper age limit

18 years

Sex

All

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

Al-Mazzeah St.

Damascus
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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

Study outputs

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