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Effect of rapid maxillary expansion on glenoid fossa and condylar position in growing patients

Submission date
31/10/2017

Recruitment status
No longer recruiting

Registration date
07/11/2017

Overall study status
Completed

Last Edited
23/11/2020

Condition category
Oral Health

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

Plain English summary of protocol

Background and study aims
Growing children may have dental crowding, crossbite (where the upper teeth fall inside the lower teeth when you bite), breathing problems, and hearing loss, due to insufficient (not enough) growth of the maxillary bone (the bone in the front of the face). Rapid maxillary extension (RME) is an orthodontic procedure that uses a device implanted in the palate to expand the maxillary bone, ultimately resulting in increasing its diameter, and eventually correcting breathing problems, hearing loss, teeth position and crossbite. The aim of this study is to investigate if RME in growing patients will result in radiographic changes at the level of glenoid fossa and nasal cavity width compared to a control group.

Who can participate?
Children aged 8 to 13 years old who have a maxillary skeletal deficiency with a crossbite.

What does the study involve?
Participants are randomly allocated to one of two groups. Those in the first group undergo rapid maxillary extension (RME) implanted. Those in the second group have no device implanted. Participants are followed up three weeks after their first visit where the RME is removed. Participants are evaluated and have x-rays. Participants are then followed up again at six months for a clinical examination and have their mouth imaging. Participants are assessed for their improvements in their crossbite.

What are the possible benefits and risks of participating?
Participants in the treatment group may benefit from enhancing nasal breathing, and eventually avoiding vital problems such as obstructive sleep apnea, preventing problems of the temporo-mandibular joints, avoiding skeletal and dental malocclusions that may require invasive orthognathic surgery later in adulthood and facilitating hearing by relieving constriction at the level of the Eustachian tubes. There are no foreseeable medical risks with taking part in participating.

Where is the study run from?
Lebanese University School of Dentistry (Lebanon)

When is the study starting and how long is it expected to run for?
March 2016 to June 2018

Who is funding the study?
Centre National de Recherche Scientifique, Lebanon (CNRS) (Lebanon)

Who is the main contact?
Dr Mona Sayegh-Ghoussoub
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
MG_002

Study information

Scientific Title
Effect of rapid Maxillary Expansion on glenoid fossa and condyle-fossa relationship in Growing Patients: Study protocol for a controlled clinical trial

Acronym
MEGP

Study objectives

In growing patients with significant maxillary skeletal deficiency in the transverse dimension with bilateral crossbite, rapid maxillary extension increases interglenoid fossa distance, condyle fossa relationship, and nasal width, compared to a control group.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Research Ethics Committee of Dental School, Lebanese University, 11/08/2015, ref: 31.04.2015

Study design
Open two-arm parallel group controlled prospective clinical trial

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
No participant information sheet available

Health condition(s) or problem(s) studied
Growing subjects, aged 8 to 13 years presenting a transverse maxillary skeletal deficiency, with bilateral crossbite involving one or more posterior teeth

Interventions
At baseline, all the patients undergo clinical examination, plaster study model casts and maxillary low-dose 3D CBCT (Cone-beam computed tomography) with an iCat® machine (Imaging Sciences International, Hatfield, Pa). Patients allocated to the treatment group will undergo rapid maxillary extension (RME) [T0], while patients in the control group will have no device implanted.

Study group: Participants included in this group undergo an RME with an expansion device (Hyrax®,Dentaurum, Ispringen, Germany). The opening of the intermaxillary suture will be checked clinically by the occurrence of an interincisal diastema and radiologically as radiolucency appearing at the same region on an occlusal X-ray.

Control group: Participants presenting the same characteristics as the study group but asking to postpone the RME, are included in this group.

A follow-up visit is scheduled three weeks after the first visit (T0), termed (T1), where patients in the RME group undergo device removal. All the patients from both groups has a clinical examination and on occlusal X Ray.

A follow-up visit is scheduled six months weeks after T1, termed (T2), where all the patients undergo a clinical examination and a repeat maxillary low-dose 3D CBCT.

Thus, participants are seen at three predefined visits.

Intervention Type
Device

Primary outcome measure
Interglenoid fossa distance is measured using specific software (ITK-SNAP, IMAGINE, CMF) at baseline and 6-month visit.

All the outcomes are radiological. Radiological data acquired with CBCT obtained at baseline and 6 months will be saved as DICOM files. 3-dimensional surface models of the anatomic structures will be built using specific software (ITK-SNAP; open-source software, www.itksnap.org; IMAGINE, open-source software, http://www.ia.unc.edu/dev/download/imagine , Cranio-Maxillo-Facial (CMF) application software, M. E. Müller Institute for Surgical Technology and Biomechanics, University of Bern, http://co-me.ch).

Secondary outcome measures
1. Condyle fossa relationships are measured using specific software (ITK-SNAP, IMAGINE, CMF) at baseline and 6-month visit
2. 3D condylar angles are measured using specific software (ITK-SNAP, IMAGINE, CMF) at baseline and 6-month visit
3. Nasal width is measured using specific software (ITK-SNAP, IMAGINE, CMF) at baseline and 6-month visit

Overall study start date
01/03/2016

Completion date
01/06/2018

Eligibility

Key inclusion criteria
1. Male or female growing subject
2. Aged 8 to 13 years
3. Presence of a transverse maxillary skeletal deficiency, with bilateral crossbite involving one or more posterior teeth (bicuspids or molars) assessed by a clinical examination
4. Presence of sufficient crown length (around 3-4mms) to provide the necessary anchorage for the RME appliance selected for the study
5. Presence of a deep palatal vault
6. Dental crowding at the start of treatment

Participant type(s)
Patient

Age group
Child

Lower age limit
8 Years

Upper age limit
13 Years

Sex
Both

Target number of participants
40

Key exclusion criteria
1. Craniofacial syndromes (such as craniosynostosis, Apert-Crouzon, Treacher-Collins, orofacial clefting, etc.)
2. Missing maxillary posterior permanent teeth (first molars)
3. Concomitant periodontal disease
4. Previous orthodontic treatment

Date of first enrolment
01/09/2016

Date of final enrolment
01/12/2017

Locations

Countries of recruitment
Lebanon

Study participating centre
Lebanese University School of Dentistry
Department of Orthodontics
Lebanese University School of Dentistry
Hadath
Beirut
Lebanon
-

Sponsor information

Organisation
Lebanese University

Sponsor details

School of Dentistry
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Beirut
Lebanon
-

Sponsor type
University/education

Website
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ROR
https://ror.org/05x6qnc69

Funder(s)

Funder type
Research organisation

Funder Name
Centre National de Recherche Scientifique, Lebanon (CNRS)

Funder Name
Lebanese University

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer reviewed journal.

Intention to publish date
15/07/2018

Individual participant data (IPD) sharing plan
The current 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?
Protocol article	protocol	01/03/2018	23/11/2020	Yes	No