Clinical Trial Protocol
Iranian Registry of Clinical Trials

02 Nov 2026

Comparison of Dimensional changes of upper airway before and after rapid maxillary expansion in children with maxillary constriction evaluated with cone beam computed tomography

Protocol summary

Summary

Objectives: The aim of this study is to evaluate dimensional changes of upper airway after rapid maxillary expansion via CBCT. Design: stage 2 trial. setting and conduct: 15 patients refering to Orthodontic department of khorasegan university requiring rapid maxillary expansion due to maxillary transverse deficiency are selected and treated with Hyrax appliances with rapid activation. CBCT images of the patients will be obtained before and 4 months after the Rapid Maxillary Expansion and upper Airway volume,nasal transverse dimensions, angular and distance landmarks will be measured before and 4 months after the treatment. Participants including major eligibility criteria: Patients with 10 to 15 years old who needs maxillary expansion due to maxillary width deficiency. Intervention: CBCT images before and 4 month after treatment. Main outcom measures: Increase of maxillary width followed by upper airway changes.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014070818404N1**
Registration date: **2014-10-19, 1393/07/27**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2014-10-19, 1393/07/27

Registrant information

Name

Sepideh Dadgar

Name of organization / entity

Azad university of Khorasegan

Country

Iran (Islamic Republic of)

Phone

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s.dadgar@khuisf.ac.ir

Recruitment status

Recruitment complete

Funding source

investigator

Expected recruitment start date

2014-02-20, 1392/12/01

Expected recruitment end date

2014-04-19, 1393/01/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of Dimensional changes of upper airway before and after rapid maxillary expansion in children with maxillary constriction evaluated with cone beam computed tomography

Public title

Evaluation of Dimensional changes of upper airway after rapid maxillary expansion

Purpose

Health service research

Inclusion/Exclusion criteria

Patients with 10 to 15 years old who needs maxillary expansion due to maxillary width deficiency.

Age

From **10 years** old to **15 years** old

Gender
Both

Phase
2-3
Groups that have been masked
No information
Sample size
Target sample size: **15**
Randomization (investigator's opinion)
N/A
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Single
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethical committee of Isfahan University Of Medical Sciences
Street address
Hezar Jirib street
City
Isfahan
Postal code
81745-313
Approval date
2015-02-20, 1393/12/01
Ethics committee reference number
493010

Health conditions studied

1

Description of health condition studied
Maxillary constriction
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
palatal width
Timepoint
before and 4 month after rapid maxillary expansion
Method of measurement
cone beam computed tomography

Secondary outcomes

1

Description
upper airway volume
Timepoint
before and 4 month after rapid maxillary expansion
Method of measurement
cone beam computed tomography

Intervention groups

1

Description
2 radiographic images taken before and 4 month after treatment taken with CBCT technique
Category
Diagnosis

Recruitment centers

1

Recruitment center
Name of recruitment center
Orthodontic department of dental faculty of Khorasgan Azad university
Full name of responsible person
Sepideh Dadgar
Street address
East Jay street,Arghavanie boulevard
City
Isfahan

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research,Islamic Azad university of Khorasgan
Full name of responsible person
Vahid Esfehanian
Street address
East jay street,Arghavanieh boulevard
City
Isfahan
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice chancellor for research,Islamic Azad university of Khorasgan
Proportion provided by this source

100

Public or private sector
empty

Domestic or foreign origin
empty

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
empty

Person responsible for general inquiries

Contact

Name of organization / entity
Islamic Azad university of Khorasgan

Full name of responsible person
Soosan Sadeghian

Position
asistant professor

Other areas of specialty/work

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post-graduate student of orthodontics

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Person responsible for updating data

Contact

Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty

Study Protocol
empty

Statistical Analysis Plan
empty

Informed Consent Form
empty

Clinical Study Report
empty

Analytic Code
empty

Data Dictionary
empty