Clinical Trial Protocol
Iranian Registry of Clinical Trials

06 Nov 2026

Evaluation of dental & skeletal changes following surgically assisted maxillary expansion with or without pterygomaxillary disjunction, and their long-term stability

Protocol summary

Summary

The aim of this study is to evaluate the skeletal and dental changes following surgically assisted maxillary expansion with or without pterygomaxillary disjunction, and their long-term stability. We perform this study on 30 Patients aged 15 to 35 years old with narrow maxilla who are referred by orthodontists for palatal expansion. Patients with a history of surgical or orthodontic treatment on maxilla, Patients with cleft lip and/or palate anomalies, syndromic patients and patients taking any drug for a long time are excluded from this study. We perform surgically assisted maxillary expansion without pterygomaxillary disjunction on 15 consecutive patients with narrow maxilla and compare them with 15 patients who have been involved in another clinical trial study (Irct registration number: IRCT138904124303N1) and have had a surgically assisted maxillary expansion with pterygomaxillary disjunction. Using CBCT, variables are measured before treatment, and 4 and 12 months after treatment. The following variables are measured in this study: 1) Maxillary width 2) Tipping of maxillary posterior teeth 3) Thickness of bone overlaying roots of posterior maxillary teeth 4) Width of floor of the nose. The examiner who measures the variables is blind to the type of treatment performed for the patient (expansion with tooth-born or bone-born appliances).

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201204244303N2**
Registration date: **2012-04-28, 1391/02/09**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2012-04-28, 1391/02/09

Registrant information

Name
Mohammad Zandi
Name of organization / entity
Hamedan University of Medical Sciences
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Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Hamedan University of Medical Sciences

Expected recruitment start date

2012-06-01, 1391/03/12

Expected recruitment end date

2014-06-01, 1393/03/11

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of dental & skeletal changes following surgically assisted maxillary expansion with or without pterygomaxillary disjunction, and their long-term stability

Public title

Evaluation of dental & skeletal changes following surgically assisted maxillary expansion with or without

pterygomaxillary disjunction, and their long-term stability

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria: Patients with narrow maxilla who are referred by orthodontists for palatal expansion Exclusion criteria: previous surgery on maxilla, previous orthodontic treatment on maxilla, presence of cleft lip and/or palate anomalies, Syndromic patients, taking any drug for a long time

Age
From **15 years** old to **35 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **30**

Randomization (investigator's opinion)
Not randomized

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committeeو Hamedan University of Medical Sciences

Street address
Hamedan University of Medical Sciences, Shahid Fahmideh street

City
Hamedan

Postal code
65178/518

Approval date
2012-04-16, 1391/01/28

Ethics committee reference number
230/9/35/16 /د/پ

Health conditions studied

1

Description of health condition studied
Narrow palate

ICD-10 code
K07.8

ICD-10 code description
Other dentofacial anomalies

Primary outcomes

1

Description
maxillary width after treatment

Timepoint
4 months and 12 months after surgery

Method of measurement
Examination of occlusion and casts

Secondary outcomes

1

Description
Thickness of bone overlaying roots of posterior maxillary teeth after treatment

Timepoint
4 months and 12 months after surgery

Method of measurement
CBCT analysis

2

Description
Width of floor of the nose after treatmemt

Timepoint
4 months and 12 months after surgery

Method of measurement
CBCT analysis

3

Description
Tipping of maxillary posterior teeth after treatment

Timepoint
4 months and 12 months after surgery

Method of measurement
CBCT analysis

Intervention groups

1

Description
]Intervention: Surgically assisted maxillary expansion without pterygomaxillary disjunction and activation of tooth-born expanders 0.5 mm a day until correction of maxillary narrowness

Category
Treatment - Surgery

2

Description
]Intervention: Surgically assisted maxillary expansion with pterygomaxillary disjunction and activation of tooth-born expanders 0.5 mm a day until correction of maxillary narrowness
Category
Treatment - Surgery

Recruitment centers

1

Recruitment center
Name of recruitment center
Hamedan University of Medical Sciences
Full name of responsible person
Dr. Mohammad Zandi
Street address
Department of oral and maxillofacial surgery, Faculty of Dentistry, Shahid Fahmideh street
City
Hamedan

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Hamedan University of Medical Sciences
Full name of responsible person
Dr. Tavilani, Vice- Chancellor of university in research affairs
Street address
Hamedan University of Medical Sciences, Shahid Fahmideh street
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Hamedan
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Hamedan University of Medical Sciences
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
Faculty of Dentistry, Hamedan University of Medical Sciences
Full name of responsible person
Dr. Mohammad Zandi
Position
Associate Professor of Oral and Maxillofacial surgery
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Person responsible for updating data

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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