

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Aug 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

Country

Iran (Islamic Republic of)

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Email address

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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 Committee, 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 treatment

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

Other areas of specialty/work

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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