

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Sep 2026

Evaluation of skeletal and dental changes following surgically assisted maxillary expansion using bone-born versus tooth-born appliances

Protocol summary

Summary

The aim of this study is to evaluate the skeletal and dental changes following surgically assisted maxillary expansion using bone-born versus tooth-born appliances. 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 randomly assign patients into two groups. For patients in one group tooth-born expanders and for patients in the other group bone-born appliances are used. 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: **IRCT138904124303N1**

Registration date: **2010-08-01, 1389/05/10**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2010-08-01, 1389/05/10

Registrant information

Name

Mohammad Zandi

Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Hamedan University of Medical Sciences

Expected recruitment start date

2010-08-01, 1389/05/10

Expected recruitment end date

2012-12-31, 1391/10/11

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of skeletal and dental changes following surgically assisted maxillary expansion using bone-born versus tooth-born appliances

Public title

Evaluation of skeletal and dental changes following surgically assisted maxillary expansion using bone-born versus tooth-born appliances

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)

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

2010-05-03, 1389/02/13

Ethics committee reference number

24087/9/35/16/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

2

Description

Tipping of maxillary posterior teeth after treatment

Timepoint

4 months and 12 months after surgery

Method of measurement

CBCT analysis

3

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

4

Description

Width of floor of the nose after treatment

Timepoint

4 months and 12 months after surgery

Method of measurement

CBCT analysis

Secondary outcomes

empty

Intervention groups

1

Description

Intervention: Activation of bone-born expanders 0.5 mm a day until correction of maxillary narrowness

Category

Treatment - Devices

2

Description

]Intervention: Activation of tooth-born expanders 0.5 mm a day until correction of maxillary narrowness

Category

Treatment - Devices

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. Ghaleiha, Vice- Chancellor of university in research affairs

Street address

Hamedan University of Medical Sciences, Shahid Fahmideh street

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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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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