

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Sep 2026

A clinical trial to compare the effect of rhBMP-2 injection and non-injection on palatal expansion in cleft lip and palate patients

Protocol summary

Summary

Objective: To compare the effect of rhBMP-2 injection and non-injection on palatal expansion in cleft lip and palate patients. Design: A single-blind randomized clinical trial. Study population: Cleft lip and palate patients who need alveolar bone grafting referring to Dental Clinic of Mashhad Faculty of Dentistry. Inclusion criteria: cleft lip and palate patients; aged over 11 years showing after puberty stage (before CS3) based on cervical vertebral stadium (CVS). Exclusion criteria: Having certain systemic diseases; unwillingness to continue the study. Sample size: 16 cases. Study intervention: The control group underwent standard alveolar bone grafting, and the intervention group receiving standard alveolar bone grafting with rhBMP-2 injection. Study outcome: evaluation and comparison of the width between canines, width between the first premolars, width between the first permanent molars, as well as volume and density of alveolar bone defects with cone beam computed tomography (CBCT) in the intervention and control groups before, as well as immediately and three months after the intervention.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017051533974N1**

Registration date: **2017-06-25, 1396/04/04**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2017-06-25, 1396/04/04

Registrant information

Name

Sahar Irani

Name of organization / entity

Mashhad University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 38823255

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Recruitment status

Recruitment complete

Funding source

Mashhad University of Medical Sciences

Expected recruitment start date

2017-07-23, 1396/05/01

Expected recruitment end date

2018-07-23, 1397/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A clinical trial to compare the effect of rhBMP-2 injection and non-injection on palatal expansion in cleft lip and palate patients

Public title

The effectiveness of rhBMP-2 injected on palatal expansion.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: cleft lip and palate patients; aged over 11 years showing after puberty stage (before CS3) based on cervical vertebral stadium (CVS). Exclusion criteria: Having certain systemic diseases; unwillingness to continue the study

Age

From **11 years** old

Gender

Both

Phase

1

Groups that have been masked

No information

Sample size

Target sample size: **16**

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 of Mashhad University of Medical Sciences

Street address

Vice Chancellor for Research, Mashhad University of Medical Sciences, Ghoreishi building, Daneshgah Street

City

Mashhad

Postal code

Approval date

2015-10-14, 1394/07/22

Ethics committee reference number

IR.mums.sd.REC.1394.26

Health conditions studied

1

Description of health condition studied

Cleft lip and palate patients

ICD-10 code

Q37

ICD-10 code description

Cleft palate with cleft lip

Primary outcomes

1

Description

Width between canines

Timepoint

Before, as well as immediately and 3 months after intervention

Method of measurement

Cone beam computed tomography (CBCT)

2

Description

First pre-cooled

Timepoint

Before, as well as immediately and 3 months after intervention

Method of measurement

Cone beam computed tomography (CBCT)

3

Description

Volume and density of alveolar bone defects

Timepoint

Before, as well as immediately and 3 months after intervention

Method of measurement

Cone beam computed tomography (CBCT)

4

Description

First permanent molar

Timepoint

Before, as well as immediately and 3 months after intervention

Method of measurement

Cone beam computed tomography (CBCT)

Secondary outcomes

empty

Intervention groups

1

Description

Control group: Who is revising standard alveolar bone grafting, the effectiveness of skeletal and dental are examining 4 months after intervention before, as well as immediately and 3 months after intervention.

Category

Treatment - Surgery

2

Description

Interventional group: Who is revising standard alveolar bone grafting with rhBMP-2 injection, the effectiveness of skeletal and dental are examining 4 months after intervention before, as well as immediately and 3

months after intervention.

Category

Treatment - Surgery

Recruitment centers**1****Recruitment center****Name of recruitment center**

Mashhad Faculty of Dentistry Dental Clinic

Full name of responsible person

Sahar Irani

Street address

Dental Clinic of Mashhad Faculty of Dentistry,
Opposite Mellat Park, Vakilabad Blvd

City

Mashhad

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Mashhad University of Medical Sciences

Full name of responsible person

Mohsen Tafaghodi

Street address

Vice Chancellor for Research, Mashhad University of
Medical Sciences, Ghoreishi building, Daneshgah
Street

City

Mashhad

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Mashhad 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**

Mashhad Faculty of Dentistry

Full name of responsible person

Sahar Irani

Position

Orthodontic Residents

Other areas of specialty/work**Street address**

Opposite Mellat Park, Vakilabad Blvd Mashhad

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Web page address**Person responsible for updating data****Contact****Name of organization / entity**

Mashhad Faculty of Dentistry

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Web page address**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