

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Evaluating the effectiveness of rhBMP-2/ACS as compared to autogenous bone graft in the human maxillary sinus floor augmentation

Protocol summary

Summary

This prospective clinical trial is performed on 50 patients referred for insertion of dental implants in posterior areas of the maxilla requiring local bone augmentation. In the control group, autogenous bone will be used for maxillary sinus floor augmentation; while in the intervention group, rhBMP2/ACS will be used as the graft material. If both sides of the maxillary arch require sinus lifting, one side will be augmented by autogenous bone and the other side by rhBMP2/ACS. In all cases a two-staged procedure will be used for sinus lifting and implant placement. The amount and density of newly formed bone will be evaluated by CBCT two, 4, and 6 months after grafting procedure. Furthermore, after 6 months, a biopsy from the implant site will be performed at the time of implant surgery. The specimens will be evaluated by light microscope. After implant placement, patients will be re-examined in terms of implant success and bone resorption every 6 months for a total period of 3 years.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138901243703N1**

Registration date: **2010-03-20, 1388/12/29**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2010-03-20, 1388/12/29

Registrant information

Name

Majid Beshkar

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

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Email address

beshkar@razi.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2010-03-20, 1388/12/29

Expected recruitment end date

2011-03-20, 1389/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluating the effectiveness of rhBMP-2/ACS as compared to autogenous bone graft in the human maxillary sinus floor augmentation

Public title

Evaluating the effectiveness of rhBMP-2/ACS as compared to autogenous bone graft in the human maxillary sinus floor augmentation

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: All patients older than 18 years requiring dental implant in the posterior maxilla

Exclusion Criteria: Sinusitis and other sinus pathologies, periodontal disease or active infection in the surgical field, History of unsuccessful sinus lift procedure

Age

From **18 years** old to **80 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **50**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Tehran University of Medical Sciences

Street address
Ghods St., Enghelab St.

City
Tehran

Postal code

Approval date
2010-01-20, 1388/10/30

Ethics committee reference number
1388/12/hgt

Health conditions studied

1

Description of health condition studied
Dental Implant

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
bone height

Timepoint
Every 2 months

Method of measurement
Radiography

Secondary outcomes

1

Description
Dental implant success

Timepoint
Every one year

Method of measurement
Radiography

Intervention groups

1

Description
Autogenous bone graft harvested from tuberosity during surgery

Category
Treatment - Surgery

2

Description
rhBMP2/ACS which consists of a collagen sponge soaked with a solution

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Tehran University of Medical Sciences

Full name of responsible person

Street address

City
Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
Majid Beshkar

Street address
Ghods st, Enghelab st

City
Tehran

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Tehran 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

Ghods st, Enghelab st,

City

Tehran

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Web page address**Person responsible for general inquiries****Contact****Name of organization / entity**

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Full name of responsible person

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Position

Resident of Oral and Maxillofacial Surgery

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Tehran University of Medical Sciences and Health
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Full name of responsible person

Majid Beshkar

Position

Resident of Oral and Maxillofacial Surgery

Other areas of specialty/work**Street 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