Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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)

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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

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Ghods st, Enghelab st

City
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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
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

Person responsible for general inquiries

Contact
Name of organization / entity
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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