

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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

+98 21 8869 7910

###### 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***Person responsible for general inquiries****Contact****Name of organization / entity**

Tehran University of Medical Sciences and Health Services, Faculty of Dentistry

**Full name of responsible person**

Majid Beshkar

**Position**

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Tehran University of Medical Sciences and Health Services

**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*