

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

02 Jul 2026

### Comparative histological and radiological results of Nano-crystalline hydroxyapatite (Ostim) and Bio-oss used in maxillary sinus augmentation: a human study

#### Protocol summary

##### Summary

The aim of present study was Comparative histological and radiological results of Nano-crystalline hydroxyapatite (Ostim) and Bio-oss used in maxillary sinus augmentation: a human study the critical inclusion and exclusion criteria were 1-maxillary partial (unilateral or bilateral) edentulism or complete edentulism 2- Residual bone height between the sinus floor and the alveolar crest less than 5 mm. 10 patients (5 patients test group and 5 patients control group) selected randomly and sinus augmentation was performed with Ostim (test group) and Bio-oss ( control group) .Parameters evaluated were percentage of new bone formation, and percentage of residual graft material and residual bone height between the sinus floor and the alveolar crest in baseline and after sinus augmentation. .

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201204157128N2**

Registration date: **2012-12-10, 1391/09/20**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2012-12-10, 1391/09/20

##### Registrant information

##### Name

Adileh Shirmohammadi

##### Name of organization / entity

Tabriz University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 41 1335 5965

##### Email address

shirmohamadia@tbzmed.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Tabriz university of medical science

##### Expected recruitment start date

2012-04-03, 1391/01/15

##### Expected recruitment end date

2012-12-05, 1391/09/15

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparative histological and radiological results of Nano-crystalline hydroxyapatite (Ostim) and Bio-oss used in maxillary sinus augmentation: a human study

##### Public title

Comparative histological and radiological results of two bone grafts used in maxillary sinus augmentation

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion criteria; maxillary partial (unilateral or bilateral) edentulism or complete edentulism; Residual bone height between the sinus floor and the alveolar crest less than 5 mm. The exclusion criteria: smokers; pregnant women; maxillary sinus pathology; cystic lesions of the maxillary sinus; systemic disease; e.g unstable diabetes; heart disease; malignancies; radiotherapy for head and neck especially maxilla; autoimmune diseases; metabolic

diseases that becomes difficult to the healing of the soft and hard tissue (e.g osteoporosis, hyperparathyroidism ,...); steroids and immunosuppressive drugs; bisphosphonates drug; untreated periodontal disease and periapical disease especially in teeth; which are close to the sinuses.

**Age**

From **40 years** old to **80 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **10**

**Randomization (investigator's opinion)**

Randomized

**Randomization description****Blinding (investigator's opinion)**

Double blinded

**Blinding description****Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Tabriz University of Medical Sciences- Dentistry faculty

**Street address**

Golgasht street,daneshgah street,Tabriz, Iran

**City**

Tabriz

**Postal code****Approval date**

2012-09-27, 1391/07/06

**Ethics committee reference number**

91127

**Health conditions studied****1****Description of health condition studied**

maxillary sinus augmentation due to bone resorbtion

**ICD-10 code**

M86-M90

**ICD-10 code description**

Other osteopathies

**Primary outcomes****1****Description**

new bone formation after sinus augmentation

**Timepoint**

After 5 month

**Method of measurement**

Microscope

**Secondary outcomes****1****Description**

residual bone graft after 5 month

**Timepoint**

After 5 month

**Method of measurement**

microscope

**2****Description**

bone density

**Timepoint**

After 5 month

**Method of measurement**

CBCT

**Intervention groups****1****Description**

control group: use of bio-oss in sinus augmentation

**Category**

Treatment - Surgery

**2****Description**

Intervention:use of ostim in sinus augmentation

**Category**

Treatment - Surgery

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

Dentistry faculty of Tabriz, Periodontics ward

**Full name of responsible person**

Dr Adileh Shirmohamadi

**Street address**

Golgasht street, Daneshgah street,

**City**

Tabriz

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Tabriz University of Medical Sciences

**Full name of responsible person**

Dr. Pourabbas

**Street address**

Tabriz University of Medical Sciences, Golgasht street,  
Daneshgah street, Tabriz, Iran

**City**

Tabriz

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

Yes

**Title of funding source**

Tabriz 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**

Tabriz University of Medical Sciences

**Full name of responsible person**

Nasrin Rahmanpour

**Position**

Periodontics resident

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## Person responsible for scientific inquiries

**Contact****Name of organization / entity**

Tabriz University of Medical Sciences-dentistry faculty

**Full name of responsible person**

Adileh Shirmohammadi

**Position**

Periodontist/associated professor

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**Web page address**

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## Person responsible for updating data

**Contact****Name of organization / entity**

Tabriz University of Medical Sciences, Dentistry faculty

**Full name of responsible person**

Adileh Shirmohamadi

**Position**

Periodontist/associated professor

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

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**Web page address**

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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*