

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Jul 2026

The efficacy of Simvastatin in maxillary sinus augmentation: a randomized controlled trial (histomorphometric and radiographic evaluation)

Protocol summary

Summary

Twelve patients (24 sinuses) will be selected from those presenting to periodontology department of Dental Faculty of Tehran University of Medical Sciences who desiring to receive maxillary posterior implants and did not have sufficient bone as determined on cone beam computerized scan (CBCT) for dental implant placement. Procedures will be done under local anesthesia with different anesthetic agents depending on patient medical history and investigator preference. By a full thickness flap reflection, the lateral sinus wall will be exposed and osteotomy will be performed with rotary burs. The sinus membrane will be elevated. A xenograft alone will be placed in one side and a xenograft + simvastatin will be placed in the contralateral side. Randomization by toss of a coin will be used to determine the test and control sites. A resorbable collagen membrane will be hydrated in sterile saline and will be placed over the lateral window. A postoperative CBCT will be taken to ensure that all graft material was in place. Appropriate antibiotics, analgesics for 7-10 days and chlorhexidine gluconate 0.2% for two weeks, will be prescribed. After 6 months, a trephine with 2.3 mm internal diameter and 10 mm length will be used to harvest a bone core for histomorphometric analysis as the first step in the implant osteotomy. The cores will be harvested from both test and control sites by investigators in a manner which will not compromise the implant receptor sites. The reference points will be determined by these landmark points and used for measurements of bone height and density for all CBCTs in each patient.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016062527240N1**

Registration date: **2016-07-16, 1395/04/26**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2016-07-16, 1395/04/26

Registrant information

Name

Sahar Rafiei

Name of organization / entity

Dental Faculty of Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Dental Faculty of Tehran University of Medical Sciences

Expected recruitment start date

2016-08-31, 1395/06/10

Expected recruitment end date

2017-04-30, 1396/02/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The efficacy of Simvastatin in maxillary sinus augmentation: a randomized controlled trial (histomorphometric and radiographic evaluation)

Public title

The efficacy of Simvastatin in maxillary sinus

augmentation: a randomized controlled trial (histomorphometric and radiographic evaluation)

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Patients who desiring to receive maxillary posterior implants and did not have sufficient bone as determined on cone beam computerized scan (CBCT) for dental implant placement; patients will be partially or completely edentulous in the posterior maxilla, all of them will need bilateral maxillary sinus augmentation surgeries. Exclusion criteria: Patients needing antibiotic prophylaxis for dental procedures; any sinus pathology (acute or chronic) contraindicating the sinus grafting; patients with systemic disease that contraindicating any oral surgeries; patients who smoked more than 10 cigarettes daily; women who were pregnant or wished to become pregnant during the period of the study; patients under 18 years of old; patients with diseases or use of medications known to affect bone metabolism, tissue regeneration and repair such as corticosteroids, bisphosphonates and etc.; patients with a history of alcoholism or recreational drug abuse; patients who had a history of cancer, radiation to the head and neck in the last 18 months.

Age

No age limit

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: 24

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Randomization by toss of a coin will be used to determine the test and control sites.

Secondary Ids

1

Registry name

Ethics committee of Tehran University of Medical Sciences

Secondary trial Id

IR.TUMS.REC.1394.2203

Registration date

2016-03-09, 1394/12/19

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tehran University of Medical Sciences

Street address

Keshavarz Bulvar, Tehran, Iran

City

Tehran

Postal code

Approval date

2016-03-09, 1394/12/19

Ethics committee reference number

IR.TUMS.REC.1394.2203

Health conditions studied

1

Description of health condition studied

alveolar bone deficiency-maxillary sinus pneumatization

ICD-10 code

XIII

ICD-10 code description

Diseases of the musculoskeletal system and connective tissue

Primary outcomes

1

Description

Human maxillary sinus bone augmentation by zenograft with or without simvastatin

Timepoint

Preoperatively, immediately after surgery and at 6 months after sinus graft

Method of measurement

Histomorphometric and radiographic evaluation

Secondary outcomes

1

Description

New bone formation

Timepoint

At 6 months after sinus graft

Method of measurement

Histomorphometric analysis percent

2

Description

Connective tissue

Timepoint

At 6 months after sinus graft

Method of measurement

Histomorphometric analysis percent

3

Description

Residual graft material

Timepoint

At 6 months after sinus graft

Method of measurement

Histomorphometric analysis percent

4

Description

Bone height analysis

Timepoint

Preoperatively ,immediately after surgery and at 6 months after sinus graft

Method of measurement

CBCT analysis

5

Description

Bone density analysis

Timepoint

6 months after sinus graft

Method of measurement

CBCT analysis

Intervention groups

1

Description

Intervention group: zenograft + simvastatin solution

Category

Treatment - Surgery

2

Description

Control group: zenograft alone

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Peridontology Department, Dental Faculty of Tehran University of Medical Sciences, Tehran,Iran

Full name of responsible person

Chokami Rafiei Sahar

Street address

Peridontology Department, Dental Faculty of Tehran University of Medical Sciences, Tehran,Iran

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for research of Tehran University of Medical Sciences

Full name of responsible person

Dr Masoud Younesian

Street address

End of Amir Abad Avenue

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice Chancellor for research of 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

Peridontology Department, Dental Faculty of Tehran University of Medical Sciences

Full name of responsible person

Chokami Rafiei Sahar

Position

resident of periodontology

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

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Position

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Fax**Email****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