Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The efficacy of Simvastatin in maxillary sinus augmenttion: 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 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 perform with rotary burs. The sinus membrane will be elevated. zenograft alone will be placed in one side and zenograft + 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 take 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 prescribe. 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 will be harvested from both test and control site 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

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Name of organization / entity

Dental Faculty of Tehran University of Medical Sciences

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

Public title

The efficacy of Simvastatin in maxillary sinus

augmenttion: 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
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Person responsible for updating data

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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