Clinical Trial Protocol
Iranian Registry of Clinical Trials

03 Aug 2026

Radiographic analysis of the efficacy of Simvastatin in combination with bone graft with bovis origin in maxillary sinus augmentation: A randomized controlled clinical trial

Protocol summary

Study aim

Radiographic evaluation of newly formed bone in augmented human sinus with xenograft bone (CompactBone B.®) alone or with Simvastatin

Design

A Randomized, blinded controlled clinical trial with a parallel group design (12 patients in each group)

Settings and conduct

The surgical operations are performed in the department of periodontics. The patients are blind to the type of medicine. In the control group, after elevation of the schneiderian membrane, Bovine bone substitute soaked in normal saline is placed. on the other hand, bovine bone substitute soaked in Simvastatin are placed in the intervention group. Surgeons are not blind to the materials applied to the sites. However, examiner who evaluates the radiographs is blind to the treatment and won't conduct or supervise the surgery. CBCT (Cone Beam Computed Tomography) is used for evaluation the sinus health, morphology and residual alveolar bone height and density. For all patients radiographic assessments are recorded preoperatively, immediately and 9 months after sinus graft.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients who desire to receive maxillary posterior implants and don't have sufficient bone for dental implant placement. Exclusion criteria: Patients who have diseases or use medications known to affect bone regeneration and repair; contraindication for sinus graft; needing antibiotic prophylaxis; Women who are pregnant; Patients with a history of alcoholism or recreational drug abuse; Smoking

Intervention groups

Control side: Each subject takes antibiotic prophylaxis, 1 hour before surgery. The wall and sinus membrane are elevated. Bovine bone substitute alone is placed. A resorbable collagen membrane is placed over the lateral window. Primary flap closure obtains. A postoperative Cone Beam Computed Tomography (CBCT) is taken. The patients are asked to return to the clinic 7-10 days after surgery for postoperative assessment. Test side: Each subject takes antibiotic prophylaxis, 1 hour before surgery. The wall and sinus membrane are elevated. Simvastatin solution, 0.5 cc, is mixed with 1 cc bovine bone substitute and the mixture is placed in the site of intervention. A resorbable collagen membrane is placed over the lateral window. Primary flap closure obtains. A postoperative CBCT is taken. The patients are asked to return to the clinic 7-10 days after surgery for postoperative assessment.

Main outcome variables

Alveolar bone height and density on Cone Beam Computed Tomography

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120127008830N5**
Registration date: **2018-02-23, 1396/12/04**
Registration timing: **registered_while_recruiting**

Last update: **2018-02-23, 1396/12/04**
Update count: **0**

Registration date

2018-02-23, 1396/12/04

Registrant information

Name

Siamak Yaghobee

Name of organization / entity

Faculty of Dentistry, Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 21 8875 3510
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2018-02-09, 1396/11/20
Expected recruitment end date
2018-03-11, 1396/12/20
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Radiographic analysis of the efficacy of Simvastatin in combination with bone graft with bovis origin in maxillary sinus augmentation: A randomized controlled clinical trial

Public title
The efficacy of Simvastatin in maxillary sinus augmentation
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Patients with age over 18 Desiring to receive maxillary posterior implants Not having sufficient bone determined on CBCT for dental implant The patients are partially or completely toothless in the posterior maxilla Patients who need bilateral maxillary sinus augmentation surgeries
Exclusion criteria:
Needing antibiotic prophylaxis for dental procedures Any sinus pathology (acute or chronic) contraindicating the sinus graft surgery Patients with systemic disease contraindicating any oral surgeries Patients who smoke more than 10 cigarettes daily Women who are pregnant or wish to become pregnant during the period of the study Diseases or medications known to affect bone metabolism ,tissue regeneration and repair such as corticosteroids, bisphosphonates and etc Patients with a history of alcoholism or drug abuse Patients who have a history of cancer or radiation to the head and neck
Age
From **18 years** old
Gender
Both

Phase
4
Groups that have been masked

- Participant
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size
Target sample size: **12**
More than 1 sample in each individual
Number of samples in each individual: **2**
For each patient, Bovine bone substitute alone is placed in one side and bovine bone substitute + Simvastatin are placed in the contralateral side. This study is designed as split mouth
Randomization (investigator's opinion)
Randomized
Randomization description
Flipping a coin is used for randomization
Blinding (investigator's opinion)
Triple blinded
Blinding description
Surgeons are not blind to the materials used in the site of surgery. However, examiner who performs the radiographic evaluations is blind to the treatment and doesn't conduct or supervise the surgery.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committe of Tehran University of Medical Sciences
Street address
Dentistry School, Tehran University of Medical Science, North Karegar Street
City
Tehran
Province
Tehran
Postal code
14399-55991
Approval date
2018-01-13, 1396/10/23
Ethics committee reference number
IR.TUMS.DENTISTRY.REC.1396.4212

Health conditions studied

1

Description of health condition studied
bone loss in the posterior maxillary edentulous ridge
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Alveolar bone height on Cone Beam Computed Tomograghy
Timepoint
Preoperative, immediately and 9 months after sinus graft
Method of measurement
Cone Beam Computed Tomography:Two lines which are the mesial and distal limits of the augmented area and a center point between these two lines were selected on Cone Beam Computed Tomographys that were taken. Alveolar bone height in these three lines measured and the average of these measurements was reported as mean alveolar bone height.

2

Description
Alveolar bone density on Cone Beam Computed Tomograghy
Timepoint
preoperatively, immediately and at 9 months after sinus graft
Method of measurement
Cone Beam Computed Tomography

Secondary outcomes

empty

Intervention groups

1

Description
Control side: Each subject takes 2 gr amoxicillin or 600 mg clindamycin as antibiotic prophylaxis one hour before surgery. Clinical photographs are taken before, during and post-surgery. Procedures carry out under local anesthesia with different anesthetic. By reflection a full thickness flap, the lateral wall of the sinus is exposed. Osteotomy of the lateral sinus wall is performed with rotary burs. The wall and sinus membrane are elevated. Bovine bone substitute alone is placed. A resorbable collagen membrane is hydrated in sterile saline before to insertion and is placed over the lateral window. Primary flap closure will be obtained with silk or vicryl yarn. A postoperative CBCT is taken to ensure that all graft materials are in place. Appropriate antibiotics and analgesics will be prescribed for 7-10 days and chlorhexidine gluconate 0.2% will be prescribed for two weeks. The patients will be asked to return to the clinic 7-10 days after surgery for suture removal and postoperative assessment.
Category
Treatment - Surgery

2

Description
Intervention side: Each subject takes 2 gr amoxicillin or 600 mg clindamycin as antibiotic prophylaxis one hour before surgery. Clinical photographs are taken before, during and post-surgery. Procedures carry out under local anesthesia with different anesthetic. By reflection a full thickness flap, the lateral wall of the sinus is exposed. Osteotomy of the lateral sinus wall is performed with rotary burs. The wall and sinus membrane are elevated. Simvastatin solution (8 mg SMV in 0.5 cc ethanol 70%), 0.5 cc, is mixed with 1 cc bovine bone substitute and is placed in the intervention site. The same ratios of SMV to bovine bone substitute are used if any additional materials require filling sinuses. A resorbable collagen membrane is hydrated in sterile saline before to insertion and is placed over the lateral window. Primary flap closure will be obtained with silk or vicryl yarn. A postoperative CBCT is taken to ensure that all graft materials are in place. Appropriate antibiotics and analgesics will be prescribed for 7-10 days and chlorhexidine gluconate 0.2% will be prescribed for two weeks. The patients will be asked to return to the clinic 7-10 days after surgery for suture removal and postoperative assessment.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Tehran University of Medical Science, Dental faculty, Department of Periodontology
Full name of responsible person
Siamak Yaghobee
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for Research and Technology, Tehran University of Medical Sciences
Full name of responsible person

Dr Mohammadali Sahraiyan

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Central Organization of Tehran University of Medical Science, Ghods Street, Keshavarz Blvd

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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
Vice chancellor for Research and Technology, Tehran University of Medical Sciences

Proportion provided by this source
100

Public or private sector
Public

Domestic or foreign origin
Domestic

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact

Name of organization / entity
Dentistry School, Tehran University of medical Science

Full name of responsible person
Shakiba Farahani

Position
Dentistry student

Latest degree
A Level or less

Other areas of specialty/work
Dentistry student

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available