Clinical Trial Protocol
Iranian Registry of Clinical Trials

02 Jul 2026

Assessment of histological, clinical and radiographic outcomeś of maxillary sinus augmentation using two different xenograft materials: split mouth clinical trial

Protocol summary

Study aim

Evaluation and comparison of two xenografts in maxillary sinus augmentation

Design

Controlled randomized clinical trial, double blind, parallel group design of 12 patients. Coin toss will be used for randomization.

Settings and conduct

The present study will be performed at the periodontics department, Shahid Beheshti Dental School for patients who need an implant in the posterior maxilla. Tomographic radiographs are obtained and if the distance between the alveolar ridge and the floor of the maxillary sinus is less than 5 mm, they will enter the study after obtaining an informed consent. Randomization is done by tossing coins on the day of surgery. Patients are unaware of the type of grafting material used on each side of the mouth. Blinding will be performed for individuals performing clinical, radiographic, and histological evaluation.

Participants/Inclusion and exclusion criteria

Inclusion criteria: > 18 years, good general health, inadequate bone for a standard implant (< 5 mm residual alveolar bone height to the maxillary sinus floor), absence of infection or periapical lesion Exclusion criteria: smoking, O'Leary plaque index > 20%, allergy to the material used in the study, pregnancy/ lactation, uncontrolled periodontal disease, systemic disease or intake of any medication, history of sinusitis or any pathologic condition in the sinus

Intervention groups

The "intervention group" consists of the use of Bone+ (Novateb Pars, Iran) on one side and the "control group" includes the use of OCS-B (Nibec Co., Korea) on the other side of the mouth of each participant for lateral window maxillary sinus augmentation.

Main outcome variables

Sinus augmentation volume; New bone formation; Residual material; Inflammation rate; Type of inflammation; Granulation tissue; Necrotic tissue; Giant cell

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20211122053149N1**
Registration date: **2021-12-25, 1400/10/04**
Registration timing: **registered_while_recruiting**

Last update: **2021-12-25, 1400/10/04**
Update count: **0**

Registration date

2021-12-25, 1400/10/04

Registrant information

Name

Anahita Moscowchi

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 21 2990 2314

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-11-06, 1400/08/15

Expected recruitment end date

2022-03-06, 1400/12/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Assessment of histological, clinical and radiographic outcomeś of maxillary sinus augmentation using two different xenograft materials: split mouth clinical trial

Public title

Comparison of two xenografts in maxillary sinus augmentation

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

> 18 years Good general health Inadequate bone for a standard implant (< 5 mm residual alveolar bone height to the maxillary sinus floor) Absence of infection or periapical lesion

Exclusion criteria:

Smoking O'Leary plaque index > 20% Allergy to the material used in the study Pregnancy/ lactation Uncontrolled periodontal disease Systemic disease or intake of any medication History of sinusitis or any pathologic condition in the sinus

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size

Target sample size: **12**

More than 1 sample in each individual

Number of samples in each individual: **2**

In each patient the maxillary sinus on one side would be used as the test group (Bone+ xenograft), while the other side would be assigned as the control group (OCS-B xenograft).

Randomization (investigator's opinion)

Randomized

Randomization description

The study is performed as a split mouth investigation. The left or right side of each participant would be randomized into either the test group or the control group. Simple randomization will be used to select the type of material at each side. After elevation the sinus membrane, the coin toss method will be used to select the type of material in the right maxillary sinus. Bone+ would be used if the coin lands with heads side up, and OCS-B would be used if the coin lands with tails side up. The left sinus would be augmented with the other material. Only the surgeon and the person performing the randomization are aware of the sample allocation. Patients and individuals performing clinical and histological evaluations would be masked to the grouping information.

Blinding (investigator's opinion)

Double blinded

Blinding description

The principal investigator who performs randomization during surgery and the surgeon are aware of the type of material used. Participants are informed about the process of study and using two types of bone grafting materials; however, they are masked to the grouping information. The surgery would be first performed on the right sinus in each participant. After preparation of the sinus cavity, the principal investigator would randomly determine the type of substance to be used in the right sinus; the material will be given to the surgeon in such a way that the participant is prevented to get aware of the name of the material. A unique code would be assigned for each patient and sinus by the principal investigator, and all subsequent evaluations will be based on the codes. Postoperative clinical evaluation will be performed by a person who is unaware of the type of material used. Recording of pre- and post-operative radiographic information is done by an oral radiologist who has no knowledge of the type of material used based on the provided codes. The histologic samples are coded by the principal investigator and sent to the oral pathologist who is unaware of the type of grafting material used. Data analysis is also performed by a statistician based on the provided codes.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shahid Beheshti University of Medical Sciences

Street address

Daneshjoo Blv., Evin, Shahid Chamran Hwy

City

Tehran

Province

Tehran

Postal code

1983963113

Approval date

2021-03-03, 1399/12/13

Ethics committee reference number

IR.SBMU.DRC.REC.1399.111

Health conditions studied

1

Description of health condition studied
Maxillary sinus augmentation
ICD-10 code
K08.2
ICD-10 code description
Atrophy of edentulous alveolar ridge

Primary outcomes

1

Description
Sinus augmentation volume
Timepoint
6 months following maxillary sinus augmentation
Method of measurement
Computed tomography

Secondary outcomes

1

Description
New bone formation
Timepoint
6 months after intervention
Method of measurement
Histologic evaluation

2

Description
Residual material
Timepoint
6 months after intervention
Method of measurement
Histologic evaluation

3

Description
Inflammation rate
Timepoint
6 months after intervention
Method of measurement
Histologic evaluation

4

Description
Type of inflammation
Timepoint
6 months after intervention
Method of measurement
Histologic evaluation

5

Description
Normal connective tissue
Timepoint
6 months after intervention
Method of measurement
Histologic evaluation

6

Description
Granulation tissue
Timepoint
6 months after intervention
Method of measurement
Histologic evaluation

7

Description
Necrotic tissue
Timepoint
6 months after intervention
Method of measurement
Histologic evaluation

8

Description
Giant cell
Timepoint
6 months after intervention
Method of measurement
Histologic evaluation

Intervention groups

1

Description
Intervention group: Lateral window maxillary sinus augmentation using Bone+ (Novateb Pars, Iran) at one side of the participant's mouth
Category
Treatment - Surgery

2

Description
Control group: Lateral window maxillary sinus augmentation using OCS-B (Nibec, Korea) at the other side of the participant's mouth
Category
Treatment - Surgery

Recruitment centers

1

Recruitment center
Name of recruitment center
School of Dentistry, Shahid Beheshti University of

Medical Sciences
Full name of responsible person
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Sponsors / Funding sources

1

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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
Shahid Beheshti 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
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Position
Assistant professor
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
There is no further information.
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