

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Efficacy of xenograft materials in maxillary edentulous ridge augmentation: a clinical study

Protocol summary

Study aim

Investigating the effectiveness of using pure xenografts for edentulous ridge augmentation

Design

One-arm Clinical trial, phase 2 on at least 15 patients

Settings and conduct

In case of requiring sinus augmentation, the window is outlined by piezosurgery. A collagen membrane is fixed in the most apical part of the vestibular region using fixation tacks. Bovine xenograft is hydrated and applied in the sinus cavity and over the lateral wall of the edentulous ridge. The membrane is extended over the crest to cover the palatal ridge and fixed using additional tacks. The flap is released with periosteal-releasing incisions. The flap margins are coronally displaced with tension-free mattress sutures. Additional simple sutures are applied to ensure complete sealing of the incision site.

Participants/Inclusion and exclusion criteria

The inclusion criteria were partial/complete edentulism of the maxillary ridge with or without the need for maxillary sinus floor augmentation, patients requiring implant-supported fixed dentures, and availability of follow-up data of patients for a minimum of 6 months after edentulous ridge augmentation. The exclusion criteria were smoking, alcohol consumption, substance abuse, uncontrolled metabolic disorders, untreated periodontal disease, (VI) history of radiotherapy or intake of immunosuppressants, and history of intake of anti-resorptive medications.

Intervention groups

Edentulous maxillary ridge augmentation using pure xenografts

Main outcome variables

Data related to bone width and height are obtained using CBCT images on repeatable cuts with a fixed reference point such as the wall/floor of the nasal cavity/maxillary sinus. Considering the prediction of implant placement subcrestally, the width of the buccolingual ridge will be

measured at the level of 2 mm apical to the bony crest.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20211122053149N2**

Registration date: **2023-09-18, 1402/06/27**

Registration timing: **registered_while_recruiting**

Last update: **2023-09-18, 1402/06/27**

Update count: **0**

Registration date

2023-09-18, 1402/06/27

Registrant information

Name

Anahita Moscowchi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

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Email address

a.moscowchi@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-09-06, 1402/06/15

Expected recruitment end date

2023-11-06, 1402/08/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Efficacy of xenograft materials in maxillary edentulous ridge augmentation: a clinical study

Public title
Efficacy of pure xenografts in bone augmentation

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Partial/complete edentulism of the maxillary ridge with or without the need for maxillary sinus floor augmentation
Patients requiring implant-supported fixed dentures
Availability of follow-up data of patients for a minimum of 6 months after edentulous ridge augmentation.
Exclusion criteria:
Smoking Alcohol consumption Substance abuse
Uncontrolled metabolic disorders Untreated periodontal disease History of radiotherapy or intake of immunosuppressants History of intake of anti-resorptive medications

Age
From **18 years** old

Gender
Both

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **15**

Randomization (investigator's opinion)
N/A

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Single

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
2023-08-01, 1402/05/10
Ethics committee reference number
IR.SBMU.DRC.REC.1402.052

Health conditions studied

1

Description of health condition studied

Horizontal defect in maxillary ridge

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Buccolingual width of the ridge at the level of 2 mm apical to the alveolar crest

Timepoint

Measurement of ridge width at the beginning of treatment and at least 6 months after surgery

Method of measurement

Cone beam computed tomography

Secondary outcomes

1

Description

Ridge height based on a fixed point on the nasal floor or sinus floor

Timepoint

At the beginning of treatment and at least 6 months after surgery

Method of measurement

Cone beam computed tomography

2

Description

Height increase in the sinus area in cases where sinus augmentation would also been performed

Timepoint

At the beginning of treatment and at least 6 months after surgery

Method of measurement

Cone beam computed tomography

Intervention groups

1

Description

Local anesthesia is administered in the maxilla by injection of 4% articaine plus 1:100,000 epinephrine. A

mid-crestal incision is made from the most anterior tooth to 5 mm beyond the augmentation area using a 15c surgical scalpel. An oblique releasing incision is made at the mesial end of the first incision and extended beyond the mucogingival line. A full-thickness flap is reflected using a periosteal elevator. In case of requiring maxillary sinus floor augmentation, the lateral window is outlined with a 5 mm distance from the floor and anterior wall of the sinus by piezosurgery. Intentional perforation of cortical bone of the edentulous ridge is performed at 5 mm intervals using a round diamond bur. A barrier membrane of natural collagen (Bio-Gide, Geistlich Biomaterials, Switzerland) is prepared to correspond to the dimensions of the augmentation site and fixed in the most apical part of the vestibular region by using fixation tacks. Bovine xenograft material (Bio-Oss, Geistlich Biomaterials, Switzerland) is hydrated with sterile saline and applied in the sinus cavity and over the lateral wall of the edentulous ridge. The barrier membrane is extended over the crest to cover the palatal wall of the ridge and fixed in place using additional tacks. The flap is released with periosteal-releasing incisions at the flap base, and also by releasing muscle attachments at the vestibular side. The flap margins are coronally displaced with tension-free mattress sutures (poly-glycolic acid). Additional simple sutures are applied to ensure complete sealing of the incision site. Oblique incisions are approximated by using simple single sutures. The sutures are removed after 2 weeks, and the patients are instructed to refrain from using a removable partial denture during the healing period. A minimum of 6 months after surgery, CBCT of the augmented area is requested and the treatment results are assessed.

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

Anahita Moscowchi

Street address

Daneshjoo Blvd, Evin, Shahid Chamran Highway

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Afshin Zarghi

Street address

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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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Anahita Moscowchi

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

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Person responsible for updating data

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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