Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

The Effect of Allogenic Demineralized Dentin Matrix (ADDM) on healing outcome in maxillary sinus floor augmentation (Histological and Radiological examination):Clinical trial

Protocol summary

Study aim

Determining the histological and radiographic effectiveness of demineralized allogenic dentin matrix (ADDM) on healing outcome in maxillary sinus floor augmentation

Design

Clinical trial with a control group, with parallel groups, double-blind, non-randomized

Settings and conduct

In order to prepare allogenic demineralized dentin matrix, teeth with hopeless prognosis (advanced periodontal involvement, non-functioning third molar) and without root filling are extracted. After the removal of cement and enamel, the dentin is divided into particles with a size of 1 to 1.5 mm and undergoes partial demineralization.6 months after the surgery, a sample is taken with a trephine bur. The samples are examined histologically for the amount of remaining graft material and the formation of vital bone. The density and height of the bone in the area is determined by CBCT

Participants/Inclusion and exclusion criteria

Patients referred to the Faculty of Dentistry in Tabriz who are candidates for implant placement with bilateral partial edentulous or complete edentulous posterior maxillary region and maxillary sinus floor lifting surgery. The height of the remaining bone between the alveolar crest and the sinus floor 5 mm or less and it is not possible to place the implant in the posterior region of the maxilla in a single stage.

Intervention groups

On the control side xenograft and on the intervention side, allogeneic demineralized dentin matrix (ADDM) is used.

Main outcome variables

1) Determining and comparing the amount of vital bone formation in patients treated with ADDM and xenograft after 6 months 2) Determination and comparison of radiographic bone density in the posterior maxilla in patients treated with ADDM and xenograft after 6 months 3) Determination and comparison of the radiographic height of the bone in the posterior maxilla in patients treated with ADDM and xenograft after 6 months

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20241127063872N1**
Registration date: **2025-01-02, 1403/10/13**
Registration timing: **registered_while_recruiting**

Last update: **2025-01-02, 1403/10/13**
Update count: **0**

Registration date

2025-01-02, 1403/10/13

Registrant information

Name

Fatemeh Aghaziarati

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-12-21, 1403/10/01

Expected recruitment end date
2025-02-18, 1403/11/30
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The Effect of Allogenic Demineralized Dentin Matrix (ADDM) on healing outcome in maxillary sinus floor augmentation (Histological and Radiological examination):Clinical trial

Public title
Effect of Allogenic Demineralized Dentin Matrix (ADDM) on healing outcome in maxillary sinus floor augmentation
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
The height of the remaining bone between the alveolar crest and the sinus floor 5mm or less Presence of bilateral partial edentulism or complete edentulism in the posterior maxillary region
Exclusion criteria:
Pathological condition involving the sinus (cystic lesions , acute and chronic inflammatory disease and benign and malignant tumors) Medical conditions known to affect bone metabolism such as osteoporosis Drug regimen that affects the normal wound healing process ;Such as bisphosphonates and continuous use of corticosteroids History of chemotherapy or head and neck Radiotherapy at the time of surgery or the next 6 months Psychological problem that causes the patient's cooperation Sinus membrane perforation during surgery Smoking Pregnant women Systemic diseases such as uncontrolled diabetes and cardiovascular disease Presence of untreated periodontal diseases and periapical lesions in the teeth adjacent to the sinus
Age
No age limit
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **38**
More than 1 sample in each individual
Number of samples in each individual: **2**
The present study is conducted with split mouth design in patients referred to Tabriz Dental Faculty who are candidates for implant placement and maxillary sinus floor augmentation surgery. Xenograft is used on the control side and allogenic demineralized dentin matrix is used on the test side.
Randomization (investigator's opinion)
Not randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Patients do not know about control (Xenograft) and test (dentin graft). In order to blind the surgery, the first stage (dentin graft and Xenograft placement) and the second stage (sample collection and implant placement) will be performed by two surgeons.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee in Biomedical Research Faculty of Dentistry Tabriz University of Medical Sciences
Street address
TFaculty of Dentistry, Tabriz University of Medical Sciences, Golgasht St, University St
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Postal code
5166614711
Approval date
2024-11-18, 1403/08/28
Ethics committee reference number
IR.TBZMED.DENTISTRY.REC.1403.046

Health conditions studied

1

Description of health condition studied
Candidate patients for implant placement in the posterior region of the maxilla and maxillary sinus floor augmentation surgery
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
The amount of newly formed vital bone
Timepoint
6 months after maxillary sinus floor augmentation surgery

Method of measurement
Sampling is done with a Trephine bur with a diameter of 7.2 mm at the location of the implants. The collected samples are placed in 10% formalin solution and sent to the laboratory for histological examination. After routine and specific staining (Eosin and Hematoxylin and Red Alizarin), microscopic slides are prepared and after imaging with the help of Motic Image 2 software, the amount of newly formed vital bone is measured in square millimeters.

2

Description
Amount of remaining grafting material
Timepoint
6 months after maxillary sinus floor augmentation surgery
Method of measurement
Sampling is done with a Trephine bur with a diameter of 7.2 mm at the location of the implants. The collected samples are placed in 10% formalin solution and sent to the laboratory for histological examination. After routine and specific staining (Eosin and Hematoxylin and Red Alizarin), microscopic slides are prepared and after imaging with the help of Motic Image 2 software, the amount of the remaining graft material is measured in square millimeters.

3

Description
Bone density
Timepoint
6 months after maxillary sinus floor augmentation surgery
Method of measurement
Based on the Hounsfield number From the CBCT by soft App Mimics 10.01

4

Description
bone height
Timepoint
6 months after maxillary sinus floor augmentation surgery
Method of measurement
The difference in bone height from the crest of the ridge to the bottom of the sinus between before surgery and 6 months after surgery in the patient's CBCT

Secondary outcomes

empty

Intervention groups

1

Description
Intervention Group: In the surgical procedure for the intervention group, 2 cc of allogenic demineralized dentin matrix is placed. Teeth with a poor prognosis (such as non-functioning third molars) and no root fillings are extracted. Soft tissue, debris, and cementum on the root surface are removed using a sickle scaler, and the pulp inside the root is extracted with a k-file; enamel is removed with a burr.The remaining dentin is rinsed with sterile saline and processed in a bone mill to create particles sized 1 to 1.5 mm. These particles are washed in a 0.1 M sodium chloride solution, treated with 0.1 M Tris-HCl (pH 7.4) for 10 minutes, and then demineralized in 2% HNO3 (pH 1.0).To acellularize the samples, trypsin, raffinose, and sucrose are used in Hanks buffer. Finally, the samples are washed three times with a PBS solution containing penicillin and streptomycin for 10 minutes each and then disinfected by UV.
Category
Treatment - Surgery

2

Description
Control group: In control surgery Xenograft (Bone +B; Nova Teb Pars, Marzanabad, Iran) is placed.
Category
Treatment - Surgery

Recruitment centers

1

Recruitment center
Name of recruitment center
Faculty of Dentistry, Tabriz University of Medical Sciences
Full name of responsible person
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
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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
Tabriz 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
Tabriz University of Medical Sciences
Full name of responsible person
Fatemeh Aghaziarati
Position
resident
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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
Not applicable

Data Dictionary	No - There is not a plan to make this available