Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Evaluation of the success of free buccal fat pad in closure of membrane perforation in maxillary sinus lifting surgery

Protocol summary

Study aim
Determining the success rate of free buccal fat tissue in closing Schneider's membrane perforation in maxillary sinus lift surgery.

Design
A controlled, parallel-group, unblinded, randomized clinical trial on 10 patients. Computer randomization methods were used for randomization.

Settings and conduct
This study is carried out in the university dental clinic of Hamedan University of Medical Sciences and in the test group, the axilla is raised to a height of about 12 mm, and the perforation site is covered by Aluderm membrane with a thickness of 0.9 mm from Saz Ben Company. After that, the FDBA allograft material of the same company with a particle size of 1000 to 2000 is used with the product of the same company to fill the desired space.

Participants/Inclusion and exclusion criteria
Applicants for sinus floor lifting surgery in the area of the first premolar to the first molar of the upper jaw, Have perforations smaller than 5 mm in Schneider's membrane during treatment.

Intervention groups
In the test group, the membrane is raised to a height of about 12 mm and the perforation site is covered by Aluderm membrane with a thickness of 0.9 mm from Saz Ben Company. There is no special intervention in the control group.

Main outcome variables
Closing the perforation of Schneider's membrane

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20170117032025N11**
Registration date: **2024-02-18, 1402/11/29**
Registration timing: **prospective**

Last update: **2024-02-18, 1402/11/29**
Update count: **0**

Registration date
2024-02-18, 1402/11/29

Registrant information

Name
Arash Khalili

Name of organization / entity
Hamadan University Of Medical Sciences

Country
Iran (Islamic Republic of)

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+98 81 3838 0320

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a.khalili@umsha.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2024-03-20, 1403/01/01

Expected recruitment end date
2025-02-19, 1403/12/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluation of the success of free buccal fat pad in closure of membrane perforation in maxillary sinus lifting surgery

Public title
Evaluation of the success of free buccal fat pad in closure

of membrane perforation in maxillary sinus lifting surgery

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Applicants for sinus floor lifting surgery in the area of the first premolar to the first molar of the upper jaw Have perforations smaller than 5 mm in Schneider's membrane during treatment

Exclusion criteria:
Smoking History of surgery in this area

Age
From **30 years** old to **60 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **10**

Randomization (investigator's opinion)
Randomized

Randomization description
For randomization, we use the envelope shuffling method and for this purpose, we prepare 10 sheets of paper including 5 intervention sheets (Word A) and another 5 sheets of the control group (Word B) without replacement by choosing the patient in one of them. The patients are placed in one of the two groups by their choice without replacement.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Hamadan University of Medical Sciences

Street address
Hamadan of University of Medical Sciences, Shahid Fahmideh boulvard

City
Hamadan

Province
Hamadan

Postal code
7615665175

Approval date
2023-05-06, 1402/02/16

Ethics committee reference number
IR.UMSHA.REC.1402.104

Health conditions studied

1

Description of health condition studied
Perforation of Schneider's membrane

ICD-10 code
M26.02

ICD-10 code description
Maxillary hypoplasia

Primary outcomes

1

Description
Full area coverage

Timepoint
6 months after surgery

Method of measurement
By Cone-Beam Computed Tomography

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: The axilla is raised to a height of about 12 mm, and the perforation site is covered by Aluderm membrane with a thickness of 0.9 mm from Replicator Ben Company. After that, the FDBA allograft material of the same company with a particle size of 1000 to 2000 is used with the product of the same company to fill the desired space.

Category
Treatment - Surgery

2

Description
Control group: There is no intervention in the control group.

Category
Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center
Dental clinic of Hamadan University of Medical Sciences

Full name of responsible person
Dr Ali Heidari
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Hamadan of University of Medical Sciences, Shahid Fahmideh boulvard
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Hamedan University of Medical Sciences
Full name of responsible person
Dr Reza Shokohi
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Hamadan of University of Medical Sciences, Shahid Fahmideh street
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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
Hamedan 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
Hamedan University of Medical Sciences
Full name of responsible person
Dr Ali Heidari
Position
Faculty Member
Latest degree
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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
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available