

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Jul 2026

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

Protocol summary

Registration timing: **prospective**

Study aim

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

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

Update count: **0**

Registration date

2024-02-18, 1402/11/29

Design

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

Registrant information

Name

Arash Khalili

Name of organization / entity

Hamadan University Of Medical Sciences

Country

Iran (Islamic Republic of)

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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.

Recruitment status

Recruitment complete

Funding source

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.

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

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.

Trial completion date

empty

Main outcome variables

Closing the perforation of Schneider's membrane

General information

Scientific title

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

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170117032025N11**

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

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 boulevard

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 FDA 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

Street address

Hamadan of University of Medical Sciences, Shahid Fahmideh boulevard

City

Hamadan

Province

Hamadan

Postal code

6517838698

Phone

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Email

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Full name of responsible person

Dr Ali Heidari

Position

Faculty Member

Latest degree

Specialist

Other areas of specialty/work

Dentistry

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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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Email

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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

Person responsible for scientific inquiries**Contact****Name of organization / entity**

Hamedan University of Medical Sciences

Full name of responsible person

Dr Ali Heidari

Position

Faculty Member

Latest degree

Specialist

Other areas of specialty/work

Dentistry

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Person responsible for updating data**Contact****Name of organization / entity**

Hamedan University of Medical Sciences

Full name of responsible person

Dr Ali Heidari

Position

Faculty Member

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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