

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Jun 2026

The effect of window dimension and membrane usage on lateral sinus membrane elevation and soft tissue invasion to sinus cavity

Protocol summary

Study aim

The effect of window dimension and membrane usage on lateral sinus membrane elevation and soft tissue invasion to sinus cavity

Design

Study groups: Group 1: Conventional sinus lift patients (window size 7-8 mm) without membranes Group 2: Conventional sinus lift patients with absorbable membranes Group 3 :: Sinus lift patients with small window dimensions (Windows 5-4 mm) without membranes Group 4: Small-sized sinus lift patients with absorbent membranes Randomization based on the table of numbers and sample size in a total of 16 patients in each group of 4 patients

Settings and conduct

Surgery is performed in the Department of Oral and Maxillofacial Surgery, School of Dentistry, Ahvaz Jundishapur University of Medical Sciences, and the Surgery Center of the Surgeon.

Participants/Inclusion and exclusion criteria

Patients with alveolar ridge atrophy in posterior of maxilla (Class I, II, II, Kennedy) The height of the remaining ridge should be between 3-5 mm Patients without uncontrolled systemic disorder Patients who do not use factors that affect healing, such as cigarettes Patients who need to raise the sinus membrane more than 4 mm

Intervention groups

Patients with the need for sinus lift surgery to place the implant by a skilled surgeon, the surgery is determined according to the random table according to the patients' visit, the dimensions of the window and the window is created in the dimensions of 4-5 or 7-8 mm. The sinus membrane is given with very small sinus alluvium and the use of high sense tactile and allograft size 2000-1000 graft is placed in the area. Membranes are randomly placed on the window.

Main outcome variables

Creating a suitable bone around the implant with

different surgical methods

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201108049312N1**

Registration date: **2020-11-29, 1399/09/09**

Registration timing: **prospective**

Last update: **2020-11-29, 1399/09/09**

Update count: **0**

Registration date

2020-11-29, 1399/09/09

Registrant information

Name

ehsan mostajeran

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3771 2831

Email address

mostajeran.e@ajums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-01-01, 1399/10/12

Expected recruitment end date

2021-03-01, 1399/12/11

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of window dimension and membrane usage on lateral sinus membrane elevation and soft tissue invasion to sinus cavity

Public title

the effect of window dimension on sinus lift successful rate

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

alveolar ridge atrophy in posterior of maxilla remaining alveolar ridge between 3-5 millimeter the patient without any uncontrol disorder, immunosuppress, physical disorder, bisphosphonate drug usage, chemotherapy and radiotherapy on face area the patient who don't smoking the patient who need sinus membrane elevation more than 4 milliliter

Exclusion criteria:

the patient with uncontrol disorder, and some disease like: immunosuppress, physical disorder, bisphosphonate drug usage, chemotherapy and radiotherapy on face area remaining alveolar ridge more than 5 millimeter the patient who need sinus membrane elevation less than 4 milliliter the smoker patient patient with acute sinusitis

Age

From **25 years** old to **45 years** old

Gender

Both

Phase

2

Groups that have been masked

- Participant
- Data analyser

Sample size

Target sample size: **16**

Randomization (investigator's opinion)

Randomized

Randomization description

Since patients will be candidates for surgery based on referral and it is not possible to access them together at the same time, sampling will be sequential to complete the number of samples. The initial evaluator, if the input criterion is met without knowing the type of surgical technique that will be performed, randomly allocates the patient to a study group using a random number table.

Blinding (investigator's opinion)

Double blinded

Blinding description

It should be noted that the patient and the evaluator (clinical and radiological evaluation) are not aware of the type of window and whether or not to place the membranes. Of course, the patient is fully aware of the surgery and its purpose and the 4 types of techniques that can be performed, but will not know in which group it is located. The initial and final assessor will also be generally unaware of what technique has been applied to each patient

Placebo

Not used

Assignment

Factorial

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

ethics committee of ahvaz university of medical sciences

Street address

No. 119, Mohammadi Alley, Attari Ave, Sharifzade Ave, 24 metri azadegan street

City

ahvaz

Province

Khouzestan

Postal code

6193654589

Approval date

2020-10-09, 1399/07/18

Ethics committee reference number

IR.AJUMS.REC.1399.550

Health conditions studied**1****Description of health condition studied**

atrophy of maxillary alveolar ridge posteriorly

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

elevation the sinus membrane

Timepoint

Obtaining CBCT after five months after surgery

Method of measurement

Use CBCT radiography

Secondary outcomes**1****Description**

Complications during and after surgery, pain and patient comfort

Timepoint

From the time of surgery until a week later

Method of measurement

interview with patients and observation of complications

Intervention groups

1

Description

Control group: Group 1 : Patients who perform conventional sinus lift (window size 7-8 mm) without membranes

Category

Treatment - Surgery

2

Description

Intervention group: Group 2: Patients who perform conventional sinus lift with absorbent membranes.

Category

Treatment - Surgery

3

Description

Intervention group: Group 3: Patients Perform small sine lift windows (windows 5-4 mm) without membranes.

Category

Treatment - Surgery

4

Description

Intervention group: Group 4: Patients who perform small sine lift windows with absorbent membranes.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Department of Oral and Maxillofacial Surgery, School of Dentistry, Ahvaz Jundishapur University of M

Full name of responsible person

kazem khiabani savojbolaghchi

Street address

No. 119, Mohammadi Alley, Attari Ave, Sharifzade Ave, 24 metri azadegan street

City

ahvaz

Province

Khuzestan

Postal code

6193654589

Phone

+98 31 3771 2831

Email

mostajeran.e@ajums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

kazem khiabani savojbolaghchi

Street address

ahvaz jondishapur university of medical science

City

ahvaz

Province

Khuzestan

Postal code

61355715794

Phone

+98 31 3771 2831

Email

mostajeran.e@ajums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Ahvaz 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

Ahvaz University of Medical Sciences

Full name of responsible person

ehsan mostajeran

Position

oral and maxillofacial surgery resident

Latest degree

Medical doctor

Other areas of specialty/work

Dentistry

Street address

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City

ahvaz

Province

Khuzestan

Postal code

6193654589

Phone
+98 31 3771 2831
Email
mostajeran.e@ajums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Ahvaz University of Medical Sciences
Full name of responsible person
kazem khiabani savojbolaghchi
Position
associate professor of oral and maxillofacial surgery
Latest degree
Specialist
Other areas of specialty/work
Dentistry
Street address
oral and maxillofacial surgery department of dental
faculty of ahvaz jondishapor medical science
university
City
ahvaz
Province
Khuzestan
Postal code
61357115794
Phone
+98 61 3320 5168
Email
khiabani_ak@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity
Ahvaz University of Medical Sciences
Full name of responsible person
kazem khiabani savojbolaghchi
Position
associate professor
Latest degree
Specialist
Other areas of specialty/work
Dentistry
Street address
oral and maxillofacial surgery department of dental
faculty of ahvaz jondishapor medical science

university
City
ahvaz
Province
Khuzestan
Postal code
6135715794
Phone
+98 61 3320 5168
Email
khiabani_ak@yahoo.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is 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

Yes - There is 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

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

the data is related to the amount of elevation of the sinus membrane and the surrounding bone around the implant in different sizes of the lateral window with or without the use of membranes.

When the data will become available and for how long

starting patient surgery at 1 january 2021 till 1march 2021

To whom data/document is available

open access in public

Under which criteria data/document could be used

There are no special conditions

From where data/document is obtainable

Send a message to the email of the corresponding author

What processes are involved for a request to access data/document

one week

Comments