

# 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

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##### 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

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##### Province

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61355715794

##### Phone

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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

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

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##### Province

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## 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**  
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## Person responsible for updating data

### Contact

**Name of organization / entity**  
Ahvaz University of Medical Sciences  
**Full name of responsible person**  
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**Position**  
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Specialist  
**Other areas of specialty/work**  
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6135715794  
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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