

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Comparison of the success of maxillary sinus lifting surgery in pathologic sinuses versus normal sinuses: a clinical trial

#### Protocol summary

##### Study aim

To compare the success of maxillary sinus lifting surgery in pathologic sinuses versus normal sinuses

##### Design

This is a non-randomized, controlled, parallel-group, unblinded clinical trial study in which patients with and without pathological findings on maxillary sinus radiographs will undergo surgery.

##### Settings and conduct

This study will be conducted at the Hamadan School of Dentistry on 20 dental implant candidates. Patients will be assigned to intervention and control groups based on the presence or absence of increased mucosal thickness in the maxillary sinus on radiographic examination. Blinding is not possible in this study.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Age 18 to 65 years Candidates for dental implants Radiographic view showing increased mucosal thickness in the maxillary sinus (in the intervention group) Radiographic view showing no increased mucosal thickness in the maxillary sinus (in the control group) Exclusion criteria: Presence of acute sinus infection or inflammation

##### Intervention groups

Intervention group: Elevation of the floor of the maxillary sinus in the area of the first premolar to the first molar by open surgery in patients with radiographic evidence of increased mucosal thickness in the maxillary sinus  
Control group: Elevation of the floor of the maxillary sinus in the area of the first premolar to the first molar by open surgery in patients without radiographic evidence of increased mucosal thickness in the maxillary sinus

##### Main outcome variables

Primary outcome: Measuring the appropriate bone height, Measuring the amount of integrated bone

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20120215009014N553**

Registration date: **2025-03-21, 1404/01/01**

Registration timing: **prospective**

Last update: **2025-03-21, 1404/01/01**

Update count: **0**

##### Registration date

2025-03-21, 1404/01/01

##### Registrant information

##### Name

Jalal Poorolajal

##### Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 81 1838 0090

##### Email address

poorolajal@umsha.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2025-04-09, 1404/01/20

##### Expected recruitment end date

2025-06-10, 1404/03/20

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

## Scientific title

Comparison of the success of maxillary sinus lifting surgery in pathologic sinuses versus normal sinuses: a clinical trial

## Public title

Comparison of the success of maxillary sinus lifting surgery in pathologic sinuses versus normal sinuses

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

Age 18 to 65 years  
Candidates for dental implants  
Radiographic view showing increased mucosal thickness in the maxillary sinus (in the intervention group)  
Radiographic view showing no increased mucosal thickness in the maxillary sinus (in the control group)

### Exclusion criteria:

Presence of acute sinus infection or inflammation

## Age

From **18 years** old to **65 years** old

## Gender

Both

## Phase

N/A

## Groups that have been masked

*No information*

## Sample size

Target sample size: **20**

## Randomization (investigator's opinion)

Not randomized

## Randomization description

## 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

Vice-chancellor for Research and Technology,  
Hamadan University of Medical Sciences, Fahmideh Ave

##### City

Hamadan

##### Province

Hamadan

##### Postal code

6517838695

## Approval date

2025-01-12, 1403/10/23

## Ethics committee reference number

IR.UMSHA.REC.1403.642

## Health conditions studied

### 1

#### Description of health condition studied

Dental implant

#### ICD-10 code

M27.6

#### ICD-10 code description

Endosseous dental implant failure

## Primary outcomes

### 1

#### Description

Measuring the appropriate bone height

#### Timepoint

6 months after surgery

#### Method of measurement

Using radiography

### 2

#### Description

Measuring the amount of integrated bone formation

#### Timepoint

6 months after surgery

#### Method of measurement

Using radiography

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: Elevation of the floor of the maxillary sinus in the area of the first premolar to the first molar by open surgery in patients with radiographic evidence of increased mucosal thickness in the maxillary sinus

#### Category

Treatment - Surgery

### 2

#### Description

Control group: Elevation of the floor of the maxillary sinus in the area of the first premolar to the first molar by open surgery in patients without radiographic evidence of increased mucosal thickness in the maxillary sinus

#### Category

Treatment - Surgery

## Recruitment centers

1

### Recruitment center

**Name of recruitment center**

School of Dentistry in Hamadan city

**Full name of responsible person**

Negin Esmaeili

**Street address**

School of Dentistry, Hamadan University of Medical Sciences, Fahmideh Ave.

**City**

Hamadan

**Province**

Hamadan

**Postal code**

6517838695

**Phone**

+98 81 3838 0572

**Email**

drness81@gmail.com

## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**

Hamedan University of Medical Sciences

**Full name of responsible person**

Dr. Alireza Soltanian

**Street address**

Hamadan University of Medical Sciences, Fahmideh Ave

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info.research@umsha.ac.ir

**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**

Negin Esmaeili

**Position**

Dentistry Student

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Dentistry

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Hamedan University of Medical Sciences

**Full name of responsible person**

Dr. Ali Heydari

**Position**

Maxillofacial Surgeon

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Dentistry

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aliheidari55@gmail.com

## Person responsible for updating data

### Contact

**Name of organization / entity**

Hamedan University of Medical Sciences

**Full name of responsible person**

Dr. Jalal Poorolajal

**Position**

Professor of Epidemiology

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Epidemiology

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**Email**

poorolajal@umsha.ac.ir

**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