

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

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Province

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6517838695

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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

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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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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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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