Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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

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Name of organization / entity
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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
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Province
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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
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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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
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Dentistry Student
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Person responsible for updating data

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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