Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Clinical and radiographic assessment of reverse drilling technique on bone dimension and crestal bone level in closed sinus lift surgery

Protocol summary

Study aim
Evaluation of the effect of the reverse drilling technique using two different kits on alveolar ridge geometry and crestal bone stability in closed sinus lift surgery

Design
Triple-blind parallel-group randomized clinical trial

Settings and conduct
Implant Department, Faculty of Dentistry, Mashhad University of Medical Sciences

Participants/Inclusion and exclusion criteria
Patients eligible for inclusion in the study must be systemically healthy, candidates for implant placement in the posterior maxilla with a bone height of 4 to 5 millimeters in that region, require a closed sinus lift procedure, and have sufficient interarch space. Patients will be excluded if they have uncontrolled systemic diseases such as cardiovascular conditions, diabetes, or immune disorders, or if the Schneiderian membrane is perforated during surgery.

Intervention groups
In one group, the reverse drilling technique will be performed using Straumann drills (Straumann, Basel, Switzerland), while in the other group, the bone densification technique will be employed using the Versah drilling system. Specifically, Densah burs (VERSA, California, USA) will be used in reverse mode to simultaneously compact and expand the bone, thereby achieving the required vertical height.

Main outcome variables
The primary outcomes include: measurement of volumetric changes along with the amount of sinus floor elevation; marginal bone level, assessed by measuring the distance between the first implant thread and the crestal bone on periapical radiographs (in tenths of a millimeter); evaluation of Schneiderian membrane perforation using the Valsalva maneuver; initial survival rate in both groups; and insertion torque in both groups, measured using the torque meter.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20250601066010N1**
Registration date: **2025-06-03, 1404/03/13**
Registration timing: **prospective**

Last update: **2025-06-03, 1404/03/13**
Update count: **0**

Registration date
2025-06-03, 1404/03/13

Registrant information

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Zeinab Ghasemi

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2025-06-18, 1404/03/28

Expected recruitment end date
2025-06-28, 1404/04/07

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

Clinical and radiographic assessment of reverse drilling technique on bone dimension and crestal bone level in closed sinus lift surgery

Public title
Clinical and radiographic assessment of reverse drilling technique on the upper jaw dimension and bone level in sinus lift surgery
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
The patient is a candidate for implant placement in the posterior maxilla. The bone height in the posterior maxillary region is 4 to 5 millimeters. Implant placement requires a closed sinus lift. There is sufficient interarch space. The patient is in overall systemic health and does not take any medications.
Exclusion criteria:
The patient has uncontrolled systemic diseases such as cardiovascular disease, diabetes, or immune disorders. The Schneiderian membrane becomes perforated during surgery.
Age
From **18 years** old
Gender
Both

Phase
2-3
Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size
Target sample size: **30**
Randomization (investigator's opinion)
Randomized
Randomization description
In the present study, blocked randomization will be used to ensure that an equal number of participants are allocated to the intervention and control groups in successive but equal time intervals. In this way, for example, one type of treatment will be assigned to the first block, the other type to the second block, then the first type again to the third block, and so on. The advantage of blocked randomization is that it guarantees balance in the number of participants between groups. The difference in the number of individuals in each group will never exceed half the size of each block. Accordingly, envelopes will be prepared equal to the sample size, and each generated random sequence will be recorded on a separate sheet of paper. These sheets will then be placed inside sealed envelopes in the order of the generated sequence. To preserve the randomization sequence, the envelopes will be numbered on the outside accordingly. At the time of surgery, based on the order of eligible participants entering the study, one of the sealed envelopes will be opened in sequence, and the participant’s group allocation will be determined.
Blinding (investigator's opinion)
Triple blinded
Blinding description
In the present study, since two different kits—Straumann and Densah—will be used for reverse drilling, blinding of the surgeon is not feasible. However, the patients and the individual responsible for clinical and radiographic evaluations will be blinded to group allocation.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research Ethics Committees of School of Dentistry - Mashhad University of Medical Sciences
Street address
Vakil abad blvd.
City
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Province
Razavi Khorasan
Postal code
9177948959
Approval date
2025-04-26, 1404/02/06
Ethics committee reference number
IR.MUMS.DENTISTRY.REC.1404.024

Health conditions studied

1

Description of health condition studied
Closed sinus lift
ICD-10 code
K08.21
ICD-10 code description
Moderate atrophy of the maxilla

Primary outcomes

1

Description
The extent of sinus floor augmentation
Timepoint
3 months post-augmentation
Method of measurement
Assessing the vertical elevation of the sinus floor using radiographic examination

2

Description
Marginal Bone Level
Timepoint
Three months after augmentation and implant placement
Method of measurement
Measurement of the distance between the first thread of the implant and the crestal bone on periapical radiographs, recorded in tenths of a millimeter.

3

Description
Perforation of the Schneiderian membrane
Timepoint
Immediately after sinus augmentation
Method of measurement
Valsalva maneuver

4

Description
Initial survival rate
Timepoint
Three months after augmentation and implant placement
Method of measurement
Evaluating the survival rate of the implants in the follow-up session

Secondary outcomes

1

Description
Evaluating the insertion torque of the implant
Timepoint
During the implant insertion
Method of measurement
Torque meter

Intervention groups

1

Description
Intervention group: Patients undergoing closed sinus lift using the reverse drilling technique with the Straumann kit.
Category
Treatment - Devices

2

Description
Control group: Patients undergoing closed sinus lift using the commonly practiced reverse drilling technique with the Densah kit.
Category
Treatment - Devices

Recruitment centers

1

Recruitment center
Name of recruitment center
Implant department of Dental Facurlty of Mashhad University of Medical Sciences
Full name of responsible person
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Sponsors / Funding sources

1

Sponsor
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Grant name
Grant code / Reference number
4031559
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Mashhad University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Private
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
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Full name of responsible person
Ali Forouzanfar

Position
Assistant Professor of Periodontology

Latest degree
Specialist

Other areas of specialty/work
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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