

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

Name

Zeinab Ghasemi

Name of organization / entity

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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

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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 Faculty of Mashhad University of Medical Sciences

Full name of responsible person

Farid Shiezadeh

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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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

Email

ForouzanfarA@mums.ac.ir

Person responsible for general inquiries

Contact

Name of organization / entity

Mashhad University of Medical Sciences

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