

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Evaluation of clinical and radiographic conditions of implants placed with closed sinus lift technique with and without bone graft

Protocol summary

Study aim

Evaluation of clinical and radiographic conditions of implants placed with closed sinus lift technique with and without bone graft

Design

Clinical trial with control group, double-blind, randomized, on 40 patients. A random number table was used for randomization using closed envelopes

Settings and conduct

A total of 40 patients in need of implants in the posterior maxilla region with a minimum bone height of 5 mm referred to prosthodontics and implant dentistry, Mashhad Dental School, are selected for the study. Patients are randomly sorted into two groups of closed sinus lifts with and without bone graft materials by a random number table. The closed sinus lift surgical procedure for both groups is as follows: before the implant is placed, the Sinus lift is closed. Then, in one group, the bone graft material is used simultaneously as elevating the sinus lift. In the other group, this procedure is performed without the graft material, and then the implant is placed. Dental CBCT images are taken before surgery and six months after surgery. In addition, PA radiographic images are also taken before surgery, instantly after surgery, 3 and 6 months later. Bone height is measured and evaluated at different distances with those images.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1. Patients over 18 years of age 2. The missing tooth in the posterior maxillary area 3. At least 5 mm bone height exclusion criteria: 1. Having a Medical contraindication for implant surgery 2. Rupture of the sinus membrane during surgery 3. Implant loss

Intervention groups

In the intervention group, the bone graft is placed concurrently with elevating the sinus in a closed method to increase the thickness and height of the bone, and then an implant is placed.

Main outcome variables

vertical bone gain, pain, swelling

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20140817018834N9**

Registration date: **2021-06-12, 1400/03/22**

Registration timing: **prospective**

Last update: **2021-06-12, 1400/03/22**

Update count: **0**

Registration date

2021-06-12, 1400/03/22

Registrant information

Name

Nahid Nasrabadi

Name of organization / entity

Shahid Sadoughi University of Medical Sciences of Yazd

Country

Iran (Islamic Republic of)

Phone

+98 35 1621 2623

Email address

nasran@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-06-15, 1400/03/25

Expected recruitment end date

2022-01-21, 1400/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Evaluation of clinical and radiographic conditions of implants placed with closed sinus lift technique with and without bone graft

Public title
closed sinus lift with and without bone graft

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 1. Patients over 18 years of age 2. A missing tooth in the posterior maxilla 3. At least 5 mm bone height 4. The patient in need of an implant unit
Exclusion criteria:
 Medical contraindication for implant surgery Perforation of the sinus membrane during surgery Failure of implant

Age
From **18 years** old

Gender
Both

Phase
3

Groups that have been masked

- Outcome assessor
- Data analyzer

Sample size
Target sample size: **40**

Randomization (investigator's opinion)
Randomized

Randomization description
The randomization method will be simple and the Randomization unit will be individual. Randomization take place using www.randomization.com website and random numbers will be inserted in sealed envelopes. on the basis of the number in the envelope (even and odd), the patient will be allocated to the test or control group.

Blinding (investigator's opinion)
Double blinded

Blinding description
As to the study design of the possibility of blinding the participants, there is no principal investigator or clinic staff, and Each person's files and data are made available to the data analyzer and the Outcome assessor without knowing the case group or being in control.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Mashhad University of Medical Sciences_Mashhad faculty of dentistry

Street address

Vakil abad blvd, Mashhad Dental Faculty

City

Mashhad

Province

Razavi Khorasan

Postal code

9177948959

Approval date

2021-01-13, 1399/10/24

Ethics committee reference number

IR.MUMS.DENTISTRY.REC.1399.132

Health conditions studied

1

Description of health condition studied

The patient needs implant placement followed by a closed sinus lift.

ICD-10 code

K08.24

ICD-10 code description

Minimal atrophy of maxilla

Primary outcomes

1

Description

Bone height at the time of implant placement and 3 and 6 months after surgery

Timepoint

Bone height at the time of implant placement and 3 and 6 months after surgery

Method of measurement

The use of PA and CBCT radiographs

Secondary outcomes

1

Description

Pain and swelling after surgery

Timepoint

1-3-10 days after surgery

Method of measurement

The patient is asked about the amount of pain by telephone using the VAS index on the first, third, and tenth days, and the patient is asked to rate their pain on a scale from 0 to 10 and is also asked about the presence or absence of edema. In addition, due to special conditions in COVID-19 prevalence and attracting

patient involvement and cooperation, On the third day, the patient will be examined remotely by sending a full face photo.

Intervention groups

1

Description

Intervention group: Bone graft placement is performed concurrently with sinus elevation in a closed method to increase bone thickness and height.

Category

Treatment - Surgery

2

Description

Control group: elevating the sinus lift alone and the simultaneous placement of the implant.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Mashhad Dental Facult

Full name of responsible person

Nahid Nasrabadi

Street address

Vakilabad blvd- Mashhad Dental Faculty

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Mofsen Tafaghodi

Street address

Daneshgah Street, next to Hoveyzeh Cinema,
Ghorashi Building

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tafaghodim@mums.ac.ir

Grant name

Grant code / Reference number

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

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

Mashhad University of Medical Sciences

Full name of responsible person

Nahid Nasrabadi

Position

assistant Professor Of Periodantics/Mashhad Dental
Faculty

Latest degree

Specialist

Other areas of specialty/work

Dentistry

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Contact

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Person responsible for updating data**Contact****Name of organization / entity**

Mashhad University of Medical Sciences

Full name of responsible person

Nahid Nasrabadi

Position

Assistant Professor Of Periodontology/Mashhad Dental Faculty

Latest degree

Specialist

Other areas of specialty/work

Dentistry

Sharing plan**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

there is no more information

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available