Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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, 3and 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)

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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 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 analyser

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
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Person responsible for updating data

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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 in 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