Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Clinical and radiographic investigation of implant success in osseodensification versus open sinus lift in atrophic posterior maxillary bone

Protocol summary

Study aim

Determining the symptoms and radiographic success of implant in two techniques of osteodensification and open sinus lift in the resorbed bone of the posterior maxilla

Design

A randomized triple-blind clinical trial with a control group. The study design includes two parallel groups in the 3rd phase each including 10 patients. According to the table of random numbers, patients are classified into two groups.

Settings and conduct

This study will be conducted in the Department of Maxillofacial Surgery, Kerman Dental School. Patients who are candidates for sinus lift will be randomly divided into two groups: open sinus lift and osteodensification. The study will not be blinded. The primary outcome variable will be implant success.

Participants/Inclusion and exclusion criteria

Inclusion criteria 1. The bone height in the posterior maxilla in the areas requiring implants should be about 5 mm 2. At least 2 implants should be required in the posterior maxilla for tooth reconstruction. 3. Informed consent to participate in the research project 4. CBCT and OPG of the posterior maxilla for complete bone examination 5. The maxillary ridge bone should be D3 or D4 with low density Exclusion criteria 1. The patient should be over 60 years of age or not inclined to have dental implants. 2. The patient should have systemic problems and be on medication. 3. The bone width should be insufficient and require simultaneous ridge width reconstruction surgery. 4. The sinus floor bone should be very thick and dense

Intervention groups

Patients will be divided into two groups, one group will undergo open sinus lift surgery and the other group will undergo sinus lift surgery with osteodensification.

Main outcome variables

The main variables studied include implant success and peri-implant bone height. These variables will be measured preoperatively and at 3 and 6 months postoperatively.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20240517061819N3**
Registration date: **2025-09-18, 1404/06/27**
Registration timing: **registered_while_recruiting**

Last update: **2025-09-18, 1404/06/27**
Update count: **0**

Registration date

2025-09-18, 1404/06/27

Registrant information

Name

Ali Labafchi

Name of organization / entity

Country

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-03-21, 1404/01/01

Expected recruitment end date

2025-09-21, 1404/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical and radiographic investigation of implant success in osseodensification versus open sinus lift in atrophic posterior maxillary bone

Public title

implant success in osseodensification versus open sinus lift

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

The bone height about 5 mm Maxillary ridge bone D3 or D4 with low density At least 2 implants are required in the posterior maxilla to restore teeth.

Exclusion criteria:

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **24**

Randomization (investigator's opinion)

Randomized

Randomization description

Since the two groups are supposed to have the same sample size, Patients eligible for inclusion will be divided into 2 groups using the Blocked Randomization method by one of the nurses of the relevant ward, who is not aware of the implementation of the study. Random sequences will be generated using the Random Generator program. Random allocation concealment will be done using sequentially numbered, sealed, opaque envelopes by an independent person who does not know the study process.

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

Kerman University of Medical Sciences

Street address

University campus, Haftbagh Square, shahab st.

City

kerman

Province

Kerman

Postal code

7616913555

Approval date

2024-12-23, 1403/10/03

Ethics committee reference number

IR.KMU.REC.1403.458

Health conditions studied

1

Description of health condition studied

resorbed alveolar bone

ICD-10 code

K08.8

ICD-10 code description

Other specified disorders of teeth and supporting structures

Primary outcomes

1

Description

Marginal bone sound

Timepoint

Immediately after implant placement, 3 and 6 months later

Method of measurement

By Ostell device

Secondary outcomes

empty

Intervention groups

1

Description

Control group: an open sinus lift surgery

Category

Treatment - Surgery

2

Description

Intervention group: Using the osteodensification technique

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center
dental school, kerman
Full name of responsible person
faeze javaheri
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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
Kerman 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
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
All collected data would be shared for all researchers after the participants were unidentified
When the data will become available and for how long
Access to data will start 6 months after publication
To whom data/document is available
The data would only be available for people working in academic institutions
Under which criteria data/document could be used
Data can be used for meta-analysis and systematic reviews.
From where data/document is obtainable
The data can be obtained via email from the corresponding research
What processes are involved for a request to access data/document
The new research proposal and the processes details should be e-mailed to corresponding researcher in order to get the access permission
Comments