

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 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

Iran (Islamic Republic of)

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+98 51 3551 1852

Email address

a.labafchi@kmu.ac.ir

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

Street address

Bahonar hospital, Gharani st.

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7616913555

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Email

kianooshmobasseri@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

Dr. Abedin Iranpour

Street address

University of Medical Sciences campus, Haft Bagh
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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

Kerman University of Medical Sciences

Full name of responsible person

faeze javaheri

Position

Postgraduates student

Latest degree

Medical doctor

Other areas of specialty/work

Oral & maxillofacial surgery

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Person responsible for scientific inquiries

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Position

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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