# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

10 Jun 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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**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**
Kerman University of Medical Sciences
**Full name of responsible person**
Dr. Abedin Iranpour
**Street address**
University of Medical Sciences campus, Haft Bagh Alavi Blvd., Kerman,
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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**
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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**