

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of radiographic and clinical results of crestal sinus lift surgery with and without digital surgical guide

Protocol summary

Study aim

Comparison of clinical and radiographic results of crestal sinus lift surgery with and without digital surgical guide on the posterior maxillary edentulous patient whom need sinus lift surgery

Design

Randomized clinical trial single blind The method of randomization through coding in envelopes

Settings and conduct

This clinical trial will be done in implant department of islamic azad dental school. Randomization would be through numbering in envelopes The radiologist who measure radiographic parameters and statistics specialist are blind Crestal sinus lift and implant placement are performed in patients using non-digital digital methods

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Partially edentulous in premolar and molar teeth, min 4 mm and max 7 mm vertical bone height Exclusion Criteria: Absence of systemic disease that contraindication for surgery

Intervention groups

First group: conventional implant surgery and sinus lift surgery with osteotome and mallet Second group: guided flap less implant and sinus lift surgery

Main outcome variables

Surgical procedure time. sinus membrane perforation. post surgical pain. crestal bone changes. sinus floor bone modeling. implants position

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230529058333N1**

Registration date: **2023-06-28, 1402/04/07**

Registration timing: **prospective**

Last update: **2023-06-28, 1402/04/07**

Update count: **0**

Registration date

2023-06-28, 1402/04/07

Registrant information

Name

Mahsa Enssi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2258 5446

Email address

mahsa.enssi@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-07-06, 1402/04/15

Expected recruitment end date

2023-09-06, 1402/06/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of radiographic and clinical results of crestal sinus lift surgery with and without digital surgical guide

Public title

Comparison of clinical and radiographic results of crestal sinus lift surgery with and without digital surgical guide

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Partial maxillary edentulous in molar or premolar region
Available residual bone height from the alveolar crest to the sinus floor, ranging from 4 to 7 mm Available residual width 6 mm
Periodontal health (lack of bleeding on probing- Olerly plaque index less than 25%)

Exclusion criteria:

Systemic and local conditions incompatible with implant placement and sinus floor
Active infection in surgical site or adjacent teeth
Acute sinusitis, present of big pathologic or cystic lesion
Under 20 years old
Alcohol and drug abuse
Pregnancy
History of chemotherapy and head&neck radiotherapy in 2 years past
Lack of vertical dimension
Oblique maxillary sinus floor (<45 degree)
Smoking more 10 cigarettes per day
Avoid of signing consent letter

Age

From **20 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size

Target sample size: **24**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

The radiologist who measure radiographic parameters and statistics specialist are blind

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Islamic azad university of Medical Sciences

Street address

No 4, Neyestan 9th Ave, Pasdaran Ave, Tehran province

City

Tehran

Province

Tehran

Postal code

1946853315

Approval date

2023-04-30, 1402/02/10

Ethics committee reference number

IR.IAU.DENTAL.REC.1401.023

Health conditions studied

1

Description of health condition studied

Crestal sinus lift surgery with digital surgical guide,

Crestal sinus lift surgery without digital surgical guide

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Primary outcome: Crestal Bone Changes

Timepoint

After Surgery And After 6 Months

Method of measurement

Parallel Periapical Radiograph

2

Description

Primary outcome: Implant Angulation And Implant Distance

Timepoint

6 Months After Surgery

Method of measurement

Cone Beam Computed Tomography

3

Description

Primary outcome: Maxillary Sinus Bone Formation

Timepoint

6 Months After Surgery

Method of measurement

Cone Beam Computed Tomography

4

Description

Secondary outcome: Surgical Procedure Time

Timepoint

During Surgery

Method of measurement

Minutes, With Watch

5

Description

Secondary outcome: Post Surgery Pain

Timepoint

One Week After Surgery

Method of measurement

Pain Killers Number

6

Description

Secondary outcome: Membrane Perforation

Timepoint

During Surgery

Method of measurement

Valsalva Maneuver

Secondary outcomes

empty

Intervention groups

1

Description

Crestal sinus lift surgery with Osteotome and Mallet

Category

Treatment - Surgery

2

Description

Crestal sinus lift surgery with surgical guide And sinus lift kit

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Islamic azad university dental school

Full name of responsible person

Mohammadrza Karimi

Street address

No 9, 9th neyestan, Pasdaran Ave

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

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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

Islamic Azad University

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

Islamic Azad University

Full name of responsible person

Mohammadreza Karimi

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Periodontist

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Person responsible for scientific

inquiries

Contact

Name of organization / entity

Islamic Azad University

Full name of responsible person

Mohammadreza Karimi

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Periodontist

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Person responsible for updating data

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Full name of responsible person

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Position

Resident

Latest degree

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Dentistry

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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

Not applicable

Title and more details about the data/document

Patients information including the age, gender, pre and post surgery data/ consent form/ report, clinical trial results, and statistics analysis which has been done.

When the data will become available and for how long

It would be accessible after publishing the results.

To whom data/document is available

Researchers and others who involved in the process.

Under which criteria data/document could be used

All data could be useful for other scientific research,

From where data/document is obtainable

Email: Dr. Mohamadreza Karimi: M.karimi@iautmu.ac.ir
Dr. Mahsa Enssi: mahsa.enssi@gmail.com

What processes are involved for a request to access data/document

It should be inquired through given email addresses and can be sent after one month processing time to whom asked for.

Comments