

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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

Mohammadreza Karimi

Street address

No 9, 9th neyestan,Pasdaran Ave

City

Tehran

Province

Tehran

Postal code

1946853314

Phone

+98 21 2256 4571

Email

m.karimi@iautmu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

Mohammadreza Karimi

Street address

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

City

Tehran

Province

Tehran

Postal code

1946853315

Phone

+98 21 2256 4571

Email

m.karimi@iautmu.ac.ir

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

Street address

No 605, Negin tower, Jahan koodak street, Afrigha blv

City

Tehran

Province

Tehran

Postal code

1946853315

Phone

+98 21 8877 4746

Email

m.karimi@iautmu.ac.ir

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

Street address

No 605, Negin tower, Jahan Koodak street, Afrigha blv

City

Tehran

Province

Tehran

Postal code

1946853315

Phone

+98 21 8877 4746

Email

m.karimi@iautmu.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Islamic Azad University

Full name of responsible person

Mahsa Enssi

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Dentistry

Street address

No 14, Nasirian Ave., Mohsenian Ave., Kolahdooz St

City

Tehran

Province

Tehran

Postal code

1945984733

Phone

01222585446

Email

mahsa.enssi@gmail.com

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