Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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 premollar 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 Priodontal heath (lack of bleeding on probing- Olery 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 o 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
Mohammadreza Karimi
Street address
No 4, Neyestan 9th Ave,Pasdaran Ave,Tehran province
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Phone
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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
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Person responsible for scientific

inquiries

Contact

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Full name of responsible person
Mohammadreza Karimi

Position
Assistant professor

Latest degree
Specialist

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Periodontist

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Person responsible for updating data

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Mahsa Enssi

Position
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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