Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Maxillary Sinus Lifting: A Comparison Of Success Rate of Direct Versus Indirect Sinus Lifting for Vertical Bone Augmentation in Patients Receiving Dental Implants

Protocol summary

Study aim
To compare the direct and indirect sinus lifting techniques for maxillary bone augmentation in patients receiving Implants

Design
Single Blinded Randomized Controlled Trial

Settings and conduct
Trail will be performed in Oral and Maxillofacial Surgery Department of AFID. Two groups will be made by simple randomization of patients getting sinus lifting done for placement of Dental implants in the Maxillary Molar region . One group will get the sinus lifting done via Direct method and second group will get it done by Indirect method.Patients will be randomized by using lottery method and concealed lottery tickets will be used for the purpose of blinding.

Participants/Inclusion and exclusion criteria
INCLUSION Having physical status 1 according to ASA classification Bone Height Less than 5mm in Maxillary Molar Region EXCLUSION Pregnant women, nursing mothers, smokers Patient with infection in Maxillary Molar Region Patients Having Sinus Pathology Patient with medications that can alter pain perception.

Intervention groups
Direct Sinus Lifting will be performed in one group and indirect in Other for Augmentation of Vertical Bone Height

Main outcome variables
Post Op Pain; Post Op Swelling; Gingival Swelling; Implant Stability; Patient's Compliance

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20230926059527N2**
Registration date: **2023-09-30, 1402/07/08**
Registration timing: **registered_while_recruiting**

Last update: **2023-09-30, 1402/07/08**
Update count: **0**

Registration date
2023-09-30, 1402/07/08

Registrant information

Name
AMMAR Yasir

Name of organization / entity
Armed Forces Institute of Dentistry

Country
Pakistan

Phone
+92 346 7330822

Email address
seirraalphayankee@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-09-27, 1402/07/05

Expected recruitment end date
2023-10-07, 1402/07/15

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Maxillary Sinus Lifting: A Comparison Of Success Rate of Direct Versus Indirect Sinus Lifting for Vertical Bone Augmentation in Patients Receiving Dental Implants

Public title
Maxillary Sinus Lifting: A Comparison Of Success Rate of Direct Versus Indirect Sinus Lifting for Vertical Bone Augmentation in Patients Receiving Dental Implants
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Having physical status 1 according to ASA classification HaviBone Height Less than 5mm in Maxillary Molar Region
Exclusion criteria:
Pregnant women, nursing mothers & smokers Patient with infection in Maxillary Molar Region Patients Having Sinus Pathology Patient with medications that can alter pain perception
Age
From **35 years** old to **60 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant

Sample size
Target sample size: **20**
Randomization (investigator's opinion)
Randomized
Randomization description
Simple randomization was performed by using lottery method(Lottery chits with even and odd numbers were used. Patients with even number chits were placed in one group and with odd number chits in the second group).Allocation concealment was done using folded chits. Patients in first group got sinus lifting done by Direct Method and in second group Indirect Sinus lifting was performed.
Blinding (investigator's opinion)
Single blinded
Blinding description
Patients were blinded as they were not informed about the treatment modality used for management of their ailment.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethical Committee of AFID
Street address
AFID CMH Rawalpindi
City
Rawalpindi
Postal code
46000
Approval date
2021-07-19, 1400/04/28
Ethics committee reference number
918/Trg Dated 13 May 2020

Health conditions studied

1

Description of health condition studied
Missing tooth
ICD-10 code
K08.1
ICD-10 code description
Complete loss of teeth

Primary outcomes

1

Description
Post Op Pain
Timepoint
3rd and 5th Day after Intervention
Method of measurement
Visual Analogue Scale

2

Description
Gingival inflammation
Timepoint
3rd and 5th Day after Intervention
Method of measurement
Gingival Index

3

Description
Swelling
Timepoint
3rd and 5th Day after Intervention
Method of measurement
Observed Clinically

4

Description
Implant Stability
Timepoint
03 Months after Intervention
Method of measurement
Glickemans method

5

Description
Per Op patient Compliance
Timepoint
immediately after intervention
Method of measurement
Licekrts Scale

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group 1: Direct Sinus Lifting will performed to achieve adequate bone height for placement of dental implant in the maxillary molar region. After Caldwellluc incision the bony window will be created. After lifting the sinus membrane the bone graft will be placed in the desired area. Closure will be performed using Vicryl sutures
Category
Treatment - Surgery

2

Description
Intervention group 2: Indirect Sinus Lifting will performed to achieve adequate bone height for placement of dental implant in the maxillary molar region. After extraction of the tooth the same socket will be used to lift the sinus membrane the bone graft will be placed in the desired area. Closure will be performed using Vicryl sutures
Category
Treatment - Surgery

Recruitment centers

1

Recruitment center
Name of recruitment center
AFID
Full name of responsible person
Syed Ammar Yasir
Street address
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
AFID
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
AFID
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
Armed Forces Institute of Dentistry
Full name of responsible person
Ammar Yasir
Position
Specialty Resident
Latest degree
Medical doctor
Other areas of specialty/work
Oral and Maxillofacial Surgery
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Person responsible for scientific inquiries

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Full name of responsible person
Ammar Yasir

Position
Specialty Resident

Latest degree
Medical doctor

Other areas of specialty/work
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be 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
Not applicable

Data Dictionary
Not applicable

Title and more details about the data/document
Study Protocol, Statistical Analysis Plan, Informed Consent Clinical Study Reports will be shared

When the data will become available and for how long
After Publication Of Study

To whom data/document is available
Medical Related Individuals

Under which criteria data/document could be used
Data Can be Used by Medical related Personal for the patients going to have dental Implants in maxillary Molar Region

From where data/document is obtainable
Phone Whatsapp

What processes are involved for a request to access data/document
Data access can be asked for by telephone

Comments