

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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 Caldwelllluc 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

AFID, CMH Rawalpindi

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Email

seirraalphayankee@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

AFID

Full name of responsible person

Syed Ammar Yasir

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Postal code

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Phone

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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

Contact

Name of organization / entity

Armed Forces Institute of Dentistry

Full name of responsible person

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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

Person responsible for updating data

Contact

Name of organization / entity

Armed Forces Institute of Dentistry

Full name of responsible person

Ammar Yasir

Position

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Latest degree

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