

Clinical Trial Protocol

Iranian Registry of Clinical Trials

06 Aug 2026

Evaluation of radiological and histologic bone quality after lateral sinus lift surgery using PRF and allograft: Clinical Trial

Protocol summary

Study aim

Evaluation of histomorphometric of bone after sinus lift surgery using PRF(Platelet Rich Fibrin)

Design

Two arm parallel group randomized trial with blinded examiner and data analyzer

Settings and conduct

This study aims to evaluate the effect of PRF on bone regeneration in sinus augmentation in combination with Allograft. The study protocol will be performed in Implant Department of School of Dentistry, Mashhad University of Medical Sciences. Sinus floor augmentation using PRF and allograft in test group and Allograft alone in control group. Then histomorphometric analysis performed. In this study examiner and data analyzer will be blind.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: 1. Less than 6 mm of alveolar bone remaining in the floor of the sinus 2. Patient 25 years old and more than 3. Without history of sinus lifting in surgical site Exclusion Criteria: 1. Patient with a systemic disease like Diabetes, Immune deficiency 2. Patient with acute sinusitis

Intervention groups

Sinus lift using PRF and allograft in the test group and sinus lift just using allograft in the control group

Main outcome variables

Histomorphometric dimensions of bone after sinus lift

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190114042354N1**

Registration date: **2020-06-23, 1399/04/03**

Registration timing: **registered_while_recruiting**

Last update: **2020-06-23, 1399/04/03**

Update count: **0**

Registration date

2020-06-23, 1399/04/03

Registrant information

Name

Milad Taher

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3843 8962

Email address

taher.milad@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-01-02, 1398/10/12

Expected recruitment end date

2020-09-02, 1399/06/12

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of radiological and histologic bone quality after lateral sinus lift surgery using PRF and allograft: Clinical Trial

Public title

Evaluation of bone quality after lateral sinus lift surgery

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Less than 6 mm of alveolar bone in the floor of the sinus remained Patient 25 years old and more than Without history of sinus lift in surgical site

Exclusion criteria:

Medical contraindication for implant surgery A history of maxillary sinus inflammations. History of drug abuse

Age

From **25 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size

Target sample size: **20**

Randomization (investigator's opinion)

Randomized

Randomization description

In our study randomization takes place using Randomization.com website and using a random number that insert in pocket. Patients divide into two groups (test and control) based on odd random number that is in the pocket.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study because our intervention included blood sampling from patients in one group and no sampling in the other group, we are not capable to blind the surgeon and patients, so in our study data analyzer and outcome assessor will be kept blind.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Mashhad University of Medical Sciences

Street address

Vakil Abad Blvd, Mashhad Dental Faculty

City

Mashhad

Province

Razavi Khorasan

Postal code

9177948959

Approval date

2020-01-22, 1398/11/02

Ethics committee reference number

IR.MUMS.DENTISTRY.REC.1398.128

Health conditions studied

1

Description of health condition studied

Bone evaluation after sinus lift surgery

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Histomorphometric dimensions: From these primary measurements, the percentage of newly formed bone in the region of interest , the percentage of remaining bone substitute material , and the percentage of the contour length of the bone substitute material in contact with new bone (bone-to-bone substitute contact) would be calculated.

Timepoint

Radiographic examination before intervention and radiographic , histomorphometric evaluation 6 months after baseline

Method of measurement

Microscope. Photographed with a digital camera (Canon, Tokyo, Japan) mounted on a microscope ((Olympus BX51, Japan). The images will assess with the magnification of 40X

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: open sinus lift surgery using allograft in combination of Platelet rich fibrin. All surgery was performed with local anaesthesia, and the sinus floor augmentation using lateral window approach. after a buccal mucoperiosteal flap was raised, an osteotomy was prepared in the lateral wall of the maxillary sinus. After the Schneiderian membrane was carefully elevated, the grafting material was packed into the space between the sinus floor and the Schneiderian membrane. then a combination of freeze dried bone allograft (DIZG Deutsches Institut für Zell, Germany) and PRF preparation was inserted in sinuses of the test group. The window was covered with the membrane(Cenomembrane, Iran) before flap closure

Category

Treatment - Surgery

2

Description

Control group: sinus lift surgery using only allograftopen sinus lift surgery using allograft in combination of Platelet rich fibrin. All surgery was performed with local anaesthesia, and the sinus floor augmentation using lateral window approach. after a buccal mucoperiosteal flap was raised, an osteotomy was prepared in the lateral wall of the maxillary sinus. After the Schneiderian membrane was carefully elevated, the grafting material was packed into the space between the sinus floor and the Schneiderian membrane. then a combination of freeze dried bone allograft (DIZG Deutsches Institut für Zell, Germany) without PRF preparation was inserted in sinuses of the control group. The window was covered with the membrane(Cenomembrane, Iran) before flap closure

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Mashhad University of Medical Sciences

Full name of responsible person

Milad Taher

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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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

Mashhad University of Medical Sciences

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

Mashhad University of Medical Sciences

Full name of responsible person

Milad Taher

Position

Postgraduate student

Latest degree

Specialist

Other areas of specialty/work

Dentistry

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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

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available