

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

18 Jun 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  
**Street address**  
Vakil abad, Mashhad Dental Faculty  
**City**  
Mashhad  
**Province**  
Razavi Khorasan  
**Postal code**  
9177948959  
**Phone**  
+98 51 3806 7257  
**Email**  
Taher.Milad@yahoo.com

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**  
Mashhad University of Medical Sciences  
**Full name of responsible person**  
Milad Taher  
**Street address**  
Vakil Abad Blvd, Mashhad Dental Faculty  
**City**  
Mashhad  
**Province**  
Razavi Khorasan  
**Postal code**  
9177948959  
**Phone**  
+98 51 3806 7257

#### Fax

+98 51 3806 7257

#### Email

Taher.Milad@yahoo.com

#### 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  
**Street address**  
Azadi Square., Vakilabad Blvd., Mashhad Dental Faculty  
**City**  
Mashhad  
**Province**  
Razavi Khorasan  
**Postal code**  
9177948959  
**Phone**  
+98 51 3843 8962  
**Fax**  
**Email**  
taher.milad@yahoo.com

## Person responsible for scientific 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

**Street address**

Azadi Square., Vakilabad Blvd., Mashhad Dental Faculty

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

9177948959

**Phone**

+98 51 3843 8962

**Fax**

**Email**

taher.milad@yahoo.com

**Person responsible for updating data**

**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

**Street address**

Azadi Square., Vakilabad Blvd., Mashhad Dental Faculty

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

9177948959

**Phone**

+98 51 3843 8962

**Fax**

**Email**

taher.milad@yahoo.com

**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