

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

19 Sep 2026

### Radiologic evaluation of density and height of maxillary sinus use of CBCT with and without use of PRF and biomaterials(Randomized clinical Trial)

#### Protocol summary

##### Study aim

main goal Radiographic comparison of maxillary sinus density and height by CBCT with and without the use of PRF with biomaterials Specific goals radiographic Comparison of sinus floor density between study groups Radiographic comparison of sinus floor height between study groups functional goal: increase the success of treatment in sinus lift surgery and implant treatments, reduce recovery time, pain , complications after surgery, costs, eliminate the need for hospitalization

##### Design

The study with control and intervention group in each patient is performed in parallel without blinding on 20 people. Simple randomization is done with cans written on the right or left side of the patient.

##### Settings and conduct

This study is performed in the specialized dental clinic of the Azad Dentistry School of Tabriz, Randomly sinus lift with PRF and biomaterials is performed on one side. and opposite side, only biomaterials are used.

##### Participants/Inclusion and exclusion criteria

Entry requirements: Bilateral partial edentulousness or complete maxillary edentulousness: maximum height of the maxillary sinus floor bone is 5 mm on both sides : no systemic disease or inflammatory disease around the sinus : not taking drugs that disrupt grafts No entry conditions: sufficient bone height at the floor of the sinus on each site : Presence of systemic disease or inflammatory disease around the sinuses : use of drugs that disrupt grafts : Patient dissatisfaction after a complete description of the treatment process

##### Intervention groups

In this study, the split mouth method is used in such a way that in each patient there is both a control and intervention group. Randomly used PRF with biomaterials are used on one side of the patient's sinus lift surgery, and on the other side the transplant is performed only through biomaterials.

##### Main outcome variables

density of sinus bone :height of sinus bone :use of PRF

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20210626051717N1**

Registration date: **2021-12-29, 1400/10/08**

Registration timing: **registered\_while\_recruiting**

Last update: **2021-12-29, 1400/10/08**

Update count: **0**

##### Registration date

2021-12-29, 1400/10/08

##### Registrant information

##### Name

Rana Khalafi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 41 3281 7829

##### Email address

www.raanakhalfi@istu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2021-12-22, 1400/10/01

##### Expected recruitment end date

2022-01-21, 1400/11/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

|                                               |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
|-----------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| empty                                         |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| <b>Scientific title</b>                       | Radiologic evaluation of density and height of maxillary sinus use of CBCT with and without use of PRF and biomaterials(Randomized clinical Trial)                                                                                                                                                                                                                                                                                                                                                                                                                           |
| <b>Public title</b>                           | Evaluation effect of use PRF in maxillary sinus bone graft                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| <b>Purpose</b>                                | Treatment                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| <b>Inclusion/Exclusion criteria</b>           | <p><b>Inclusion criteria:</b><br/>Patients 20 to 80 years old male and female without systemic disease Bilateral partial edentulousness of posterior part of maxilla or complete edentulousness Maxillary sinus floor bone height below 5 mm</p> <p><b>Exclusion criteria:</b><br/>Existence of uncontrolled systemic diseases Use of immunosuppressive drugs and bisphosphonates Head and neck radiotherapy Presence of pathology and inflammatory diseases in maxillary sinus Existence of active periodontal disease behind the maxilla Irregular and chronic smoking</p> |
| <b>Age</b>                                    | From <b>20 years</b> old to <b>80 years</b> old                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| <b>Gender</b>                                 | Both                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
| <b>Phase</b>                                  | N/A                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| <b>Groups that have been masked</b>           | No information                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| <b>Sample size</b>                            | <p>Target sample size: <b>20</b></p> <p>More than 1 sample in each individual</p> <p>Number of samples in each individual: <b>2</b></p> <p>Bilateral maxillary sinus bone graft on one side with fibrin-rich platelet intervention with biomaterials and on the other without fibrin-rich platelet intervention with biomaterials only randomly</p>                                                                                                                                                                                                                          |
| <b>Randomization (investigator's opinion)</b> | Randomized                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| <b>Randomization description</b>              | Randomization in this study is done by simple randomization method with an individual unit so that at the beginning of each surgery in a patient the word left or right is written on the closed cans and by removing a can randomly and observing the word Right or left It is indicated that the fibrin-rich platelet sample is used in the patient's right sinus lift surgery or in left site and in the opposite side only biomaterials are used                                                                                                                         |
| <b>Blinding (investigator's opinion)</b>      | Not blinded                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
| <b>Blinding description</b>                   |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| <b>Placebo</b>                                | Not used                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| <b>Assignment</b>                             | Parallel                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| <b>Other design features</b>                  |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics Committee of Azad University of Medical Sciences, Tabriz Branch

##### Street address

Complex No. 2 of Islamic Azad University, Tabriz Branch. medical School .First Basmanj Road.Ahar three ways

##### City

Tabriz

##### Province

East Azarbaijan

##### Postal code

5157944533

#### Approval date

2021-12-18, 1400/09/27

#### Ethics committee reference number

IR.IAU.TABRIZ.REC.1400.132

## Health conditions studied

### 1

#### Description of health condition studied

Investigation of height and density of maxillary sinus floor bone on both sides of posterior maxilla

#### ICD-10 code

#### ICD-10 code description

## Primary outcomes

### 1

#### Description

using and not using fibrin-rich platelets with biomaterial

#### Timepoint

6 months after graft

#### Method of measurement

Is an independent variable that is measured in terms of use or non-use

### 2

#### Description

Maxillary sinus floor bone density

#### Timepoint

6 months after graft

#### Method of measurement

Hansfield number from CBCT

### 3

#### Description

Height of maxillary sinus floor bone

**Timepoint**

6 months after graft

**Method of measurement**

Based on millimeters from CBCT

**Secondary outcomes**

empty

**Intervention groups****1****Description**

Intervention group: In this study, patients aged 20-80 years without systemic disease with bilateral partial edentulousness or complete edentulousness whose remaining bone height behind the maxilla is less than 5 mm will be selected. Prior to sinus lift surgery, 20 to 40 mm of blood is collected from the patient's vein in sterile test tubes without anticoagulant and will be immediately centrifuged at 3000 rpm for 10 minutes. . As a result of the activation of the coagulation cascade and the formation of a three-layer fibrin network, including: the top layer of cell-free plasma or PPP, the middle layer of PRF and the bottom layer, which are red blood cells, will be visible in the test tube. The middle layer, or PRF, is cut with scissors from the red blood cell clots and will be used randomly with biomaterials on one side of the sinus space.

**Category**

Treatment - Surgery

**2****Description**

Control group: This study is performed as a split mouth, ie in each patient, one side of the sinus lift surgery is performed with PRF intervention and is classified as an intervention group, and on the opposite side, sinus lift surgery without PRF intervention is performed as a control group. In each patient, there is both an intervention group and a control group. On one side of the mouth, which uses PRF, it is placed in the intervention group, and on the opposite side of the mouth, which does not use PRF, it is classified in the control group.

**Category**

Treatment - Surgery

**Recruitment centers****1****Recruitment center****Name of recruitment center**

دانشکده دندانپزشکی آزاد واحد تبریز

**Full name of responsible person**

دکتر علی حسین دهقانی

**Street address**

Faculty of Dentistry.No. 2 of Islamic Azad University, Tabriz Branch. First Basmanj Road.Ahar Intersection.

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**Email**

dr.a.dehghani@iaut.ac.ir

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Islamic Azad University

**Full name of responsible person**

Dr Ehsan hashemi

**Street address**

Faculty of Dentistry. Complex No. 2 of Islamic Azad University, Tabriz Branch.First Basmanj Road.Ahar Intersection

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**Phone**

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**Email**

ranakhalafy@gmail.com

**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**

Rana khalafi

**Position**

General Dentistry Student

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Dentistry

**Street address**

No 143. Beheshti Deadend. Gajar Alley.Hojjati street

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**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Islamic Azad University

**Full name of responsible person**

Rana Khalafi

**Position**

General Dentistry student

**Latest degree**

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**Person responsible for updating data****Contact****Name of organization / entity**

Islamic Azad University

**Full name of responsible person**

Rana Khalafi

**Position**

General Dentistry Student

**Latest degree**

Medical doctor

**Other areas of specialty/work**

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**Postal code**

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**Email**

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**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

**Justification/reason for indecision/not sharing IPD**

There is no more information. "

**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