

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Radiographic comparison of density and height of posterior of maxillary bone after use of open sinus lift with and without PRF

#### Protocol summary

##### Study aim

The purpose of this study was to evaluate the effect of PRF on bone height and bone density formed in sinus lift surgery and simultaneous insertion of dental implants.

##### Design

Clinical trial with blinded postoperative care and outcome assessment, split mouth

##### Settings and conduct

In this study, 14 patients were selected in 30-80 age with bilaterally partial or complete edentulous that referred to Dental School of Tabriz for sinus lift surgery and after receiving the written consent will enter to this study. Patients will be treated with Lateral window sinus lift technique.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: The existence of bilaterally partial edentulous or complete edentulous in maxillary posterior region. Height of the remaining bone between the floor of sinus and alveolar crest be more than 4mm and less than 8 mm. Exclusion criteria: Smokers-pregnant women- pathological symptoms or cystic lesions in the sinus- acute and chronic inflammatory disease of sinus- benign and malignant tumors in sinus-systemic diseases such as uncontrolled diabetes- cardiovascular diseases - cancer- head and neck radiotherapy- autoimmune diseases that makes trouble, healing of soft and hard tissue- taking steroidal drugs, immune system suppression and bisphosphonates- the existence of untreated periodontal disease and periapical disease, especially in the adjacent teeth of sinus floor.

##### Intervention groups

The sinus floor of test group will be augmented with lateral window sinus lift surgical technique with using PFR and simultaneously implantation and in the control group, this process will be done without using the PRF.

##### Main outcome variables

Evaluation density and height of newly formed bone in the maxillary sinus by using of CBCT.

#### General information

##### Reason for update

##### Acronym

PRF (Platelet Rich Fibrin)

##### IRCT registration information

IRCT registration number: **IRCT20120702010155N4**

Registration date: **2018-03-29, 1397/01/09**

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

Last update: **2018-03-29, 1397/01/09**

Update count: **0**

##### Registration date

2018-03-29, 1397/01/09

##### Registrant information

##### Name

Mohammad Taghi Chitsazi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 41 1335 5965

##### Email address

chitsazm@tbzmed.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2018-03-01, 1396/12/10

##### Expected recruitment end date

2018-04-30, 1397/02/10

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

## Scientific title

Radiographic comparison of density and height of posterior of maxillary bone after use of open sinus lift with and without PRF

## Public title

Effect of PRF on bone density

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

The existence of bilaterally partial edentulous or complete edentulous in maxillary posterior region Height of the remaining bone between the floor of sinus and alveolar crest be more than 4 mm and less than 8 mm

### Exclusion criteria:

Smokers- Pregnant women- Pathological symptoms or cystic lesions in the sinus - Acute and chronic inflammatory disease of sinus- Benign and malignant tumors in sinus- Systemic diseases such as uncontrolled diabetes- Cardiovascular diseases- Cancer- Head and neck radiotherapy- Autoimmune diseases that makes trouble, healing of soft and hard tissue- Taking steroidal drugs, immune system suppression and bisphosphonates- The existence of untreated periodontal disease and priapical disease, especially in the adjacent teeth of sinus floor.

## Age

From **30 years** old to **80 years** old

## Gender

Both

## Phase

N/A

## Groups that have been masked

- Outcome assessor
- Data analyser

## Sample size

Target sample size: **14**

More than 1 sample in each individual

Number of samples in each individual: **2**

In each patient, one side of the sinus was considered as the test group and the other side was considered as the control group.

## Randomization (investigator's opinion)

Not randomized

## Randomization description

## Blinding (investigator's opinion)

Single blinded

## Blinding description

In this study, the patient and the investigator are aware of the study groups but a person who will evaluate the results of sinus graft surgery through CBCT radiography and the person who will analyze the results , there are no information from test and control groups.

## Placebo

Not used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics Committe of Tabriz University of Medical Sciences

##### Street address

Ethics Committe of Tabriz University of Medical Sciences, Vice Chancllor for Research of Tabriz University of Medical Sciences, Tabriz University of Medical Sciences, Golghasht street,Tabriz

##### City

Tabriz

##### Province

East Azarbaijan

##### Postal code

5166614713

#### Approval date

2018-02-26, 1396/12/07

#### Ethics committee reference number

IR.TBZMED.REC.1396.1141

## Health conditions studied

### 1

#### Description of health condition studied

Resorption of alveolar ridge in the maxillary posterior region

#### ICD-10 code

K08.2

#### ICD-10 code description

Atrophy of edentulous alveolar ridge

## Primary outcomes

### 1

#### Description

Evaluation density and height of the newly formed bone.

#### Timepoint

4 months after surgery

#### Method of measurement

By CBCT and NNT viewer software version21

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

The sinus floor of intervention group will be augmented with lateral window sinus lift technique and using PFR

and simultaneously implantation.

**Category**

Treatment - Surgery

**2****Description**

The sinus floor of control group will be augmented with lateral window sinus lift technique without PRF and simultaneously implantation.

**Category**

Treatment - Surgery

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

Faculty of Dentistry, Tabriz University of Medical Sciences

**Full name of responsible person**

Mohammad Taghi Chitsazi

**Street address**

Dental Faculty of Tabriz University of Medical Sciences, Golghasht street, Tabriz

**City**

Tabriz

**Province**

East Azarbaijan

**Postal code**

5166614711

**Phone**

+98 41 3335 5968

**Email**

chitsazm@tbzmed.ac.ir

**Web page address**

<http://dentistryfac.tbzmed.ac.ir>

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

Gingival and Dental Research Center of Tabriz Faculty of Dentistry

**Full name of responsible person**

Dr Shahriar Shahi

**Street address**

Faculty of Dentistry, Tabriz University of Medical Sciences, Golgasht Street, Tabriz

**City**

Tabriz

**Province**

East Azarbaijan

**Postal code**

5166614711

**Phone**

+98 41 3335 5968

**Email**

chitsazm@tbzmed.ac.ir

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Gingival and Dental Research Center of Tabriz Faculty of Dentistry

**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**

Tabriz University of Medical Sciences

**Full name of responsible person**

Hadi Kokabi Arasteh

**Position**

Resident of Periodontics

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Dentistry

**Street address**

Department of Periodontics., Dental Faculty., Tabriz University of Medical Sciences., Golghasht street

**City**

Tabriz

**Province**

East Azarbaijan

**Postal code**

5166614711

**Phone**

+98 41 3335 5968

**Fax****Email**

kokabih@tbzmed.ac.ir

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

Tabriz University of Medical Sciences

**Full name of responsible person**

Mohammad Taghi Chitsazi

**Position**

Professor

**Latest degree**

Master

**Other areas of specialty/work**

periodontology

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+98 41 3335 5968

**Fax****Email**

kokabih@tbzmed.ac.ir

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

Tabriz University of Medical Sciences

**Full name of responsible person**

Hadi Kokabi Arasteh

**Position**

Resident of Periodontics

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Dentistry

**Street address**

Department of Periodontics., Dental Faculty., Tabriz  
University of Medical Sciences., Golghasht street

**City**

Tabriz

**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