

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 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 PRF 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

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 5965

Fax**Email**

chitsazm@tbzmed.ac.ir

Province

East Azarbaijan

Postal code

5166614711

Phone

+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