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)

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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

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

Public title
Evaluation effect of use PRF in maxillary sinus bone graft
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
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
Exclusion criteria:
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
Age
From **20 years** old to **80 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **20**
More than 1 sample in each individual
Number of samples in each individual: **2**
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
Randomization (investigator's opinion)
Randomized
Randomization description
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
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

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
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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
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Islamic Azad University
Full name of responsible person
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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
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
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Rana khalafi
Position
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Person responsible for updating data

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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