Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Effect of Platelet Rich Fibrin (PRF) on Maxillary Schniderin Sinus Membrane Thickness Following Sinus Augmentation Surgery

Protocol summary

Study aim
The effect of PRF on maxillary sinusoidal sinus membrane thickness following Sinus lift surgery in dental school of Islamic Azad University of Tehran in 1398-1989

Design
A randomized, double-blind, placebo-controlled clinical trial

Settings and conduct
Patients in need of surgical resection of the sinus floor in 1997-98 form the study population. Radiographic observations of the CBCT cross-section at the deepest sinus point will be used to collect data.

Participants/Inclusion and exclusion criteria
In this study, 5 patients with clinical and radiographic studies requiring at least one implant in the posterior maxilla requiring bilateral sinus transplantation due to sinus pneumonia and bone resorption will be selected. CBCT x-rays will be performed for definitive effect on these patients. Inclusion criteria included height of bone crest remaining between maxillary sinus floor and maxillary bone cavity of 3 mm Exclusion criteria, acute sinus infection, chronic sinusitis, allergy, smoking, bisphosphonate treatment, uncontrolled diabetes and pregnancy.

Intervention groups
Intervention group: In the target sinus, after opening the window and lifting the Schneiderin membrane, it is placed under the Schneiderin membrane, then the PRF membrane is inserted into the bone biomaterial. Control group: In the desired sinus, after opening the window and lifting the Schneiderin membrane, it is placed under the Schneiderin membrane, without inserting the bone biomaterial PRF membrane.

Main outcome variables
Maxillary sinusoidal Schneiderin membrane thickness

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20120220009088N3**
Registration date: **2020-06-18, 1399/03/29**
Registration timing: **retrospective**

Last update: **2020-06-18, 1399/03/29**
Update count: **0**

Registration date
2020-06-18, 1399/03/29

Registrant information

Name
Saeed Sadat Mansouri

Name of organization / entity

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-04-21, 1398/02/01

Expected recruitment end date
2020-01-20, 1398/10/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Effect of Platelet Rich Fibrin (PRF) on Maxillary Schniderin Sinus Membrane Thickness Following Sinus Augmentation Surgery

Public title
Effect of PRF on Schneiderin Membrane Thickness
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients need bilateral open sinus lift The criteria for entering the study include the height of the remaining bone corset between the sinus floor and the bone cortex up to 3 mm.
Exclusion criteria:
allergies acute sinus infection chronic sinusitis smoking treatment with bisphosphonates uncontrolled diabetes pregnancy
Age
No age limit
Gender
Both

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **5**
More than 1 sample in each individual
Number of samples in each individual: **2**
Each sinus of the patient's maxilla is considered as a sample
Randomization (investigator's opinion)
Randomized
Randomization description
randomization method: simple randomization randomization unit: a maxillary sinus of patients mouth randomization instrument: dentists observation The choice between the case group and the control is completely random and by throwing dice
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
Faculty of dentistry, islamic azad university, Tehran
Street address
No 4, 10th Neyestan, Pasdaran
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Province
Tehran
Postal code
19585175
Approval date
2019-03-09, 1397/12/18
Ethics committee reference number
IR.IAU.DENTAL.REC.1397.051

Health conditions studied

1

Description of health condition studied
Maxillary sinus lift surgery
ICD-10 code
K08.26
ICD-10 code description
Severe atrophy of the maxilla

Primary outcomes

1

Description
Changing Schneiderin Membrane Thickness
Timepoint
Surgery time - one week after surgery - two months after surgery
Method of measurement
In mm on CBCT

Secondary outcomes

empty

Intervention groups

1

Description
The statistical population in this study includes 5 patients who need bilateral maxillary sinus surgery. That is, 10 sinuses are studied in 5 patients. In each patient, one sinus is selected as an intervention group and the other as a control group. The selection of the intervention side and the control side is done completely randomly by throwing dice. Sinus transplant surgery is performed on both sides of the intervention and control. The only difference between the intervention group and the control group is that in the intervention group, an L-PEF membrane is placed inside the sinus under the Schneider's sinus membrane, and the effect of L-PRF on the thickness of the maxillary Schneider sinus membrane is examined and compared. In this way, the thickness of the Schneider sinus membrane by CBCT is calculated and compared in three periods before surgery, 7 days after surgery and the second month after surgery on both sides. Intervention group: The thickness of the membrane of the Schneider sinus before surgery is calculated by CBCT. In the case of the desired sinus, which requires sinus transplant surgery by the side window method. The cut crystal of the flap is returned. Then, the side window is made by MECTRON Italy

Pizzeria or DASK Kit DENTIUM made in Korea.After elevating the Schneiderin maxillary membrane, a number of PRF membranes, which have been disinfected by the German L-PRF device, are placed under the Schneiderin membrane. Then Zenograft bonding material with granules of 1000 to 2000 BOTTIS brand is made in Germany. Finally, a German-made BASTIS JASON membrane window is placed on the side window. The flap is turned and sutured. The thickness of the Schneider's sinus membrane is calculated on day 7 after surgery and the second month after surgery by CBCT.Intervention 1 in the intervention group: maxillary sinus transplant surgery.Intervention 2 in the intervention group: placement of the L-PRF membrane under the membrane of the trigeminal sinus of the maxilla.

Category

Treatment - Surgery

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Description

Control group: Control group: The thickness of the membrane of the Schneider sinus before surgery is calculated by CBCT. In the desired sinus, which requires sinus transplant surgery by the side window method, the flap cut is cut back. Then the side window is prepared by the Italian MECTRON pizza machine or the DASK brand DENTIUM kit made in Korea.After elevating the membrane of Schneiderin's maxillary membrane in the sinus space directly below the Schneiderin membrane, the zenograft bonding material with granules 1000 to 2000 BOTTIS brand is placed in Germany. Finally, a German-made BASTIS JASON membrane window is placed on the side window. The flap is returned and sutured.Intervention 1 in the control group: maxillary sinus transplant surgery.Intervention 2 in the control group: L-PRF membrane is not located under the membrane of the trigeminal sinus maxilla . The thickness of the Schneider's sinus membrane is calculated on day 7 after surgery and the second month after surgery by CBCT. The thicknesses obtained from CBCT are compared with each other.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center
Islamic azad university dental branch of tehran
Full name of responsible person
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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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
Full name of responsible person
Saeed Sadat Mansouri
Position
Associate professor, Periodontist
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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