

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

Effect of Platelet Rich Fibrin (PRF) on Maxillary Schneiderin 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)

Phone

+98 21 2291 9455

Email address

s_sadatmansouri@dentaliau.ac.ir

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 Schneiderin 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

City

Tehran

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

Saeed Sadatmansouri

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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

Full name of responsible person

Saeed Sadat Mansouri

Position

Associate professor, Periodontist

Latest degree

Specialist

Other areas of specialty/work

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Person responsible for updating data

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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