Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Effect of Buccal Fat Pad Derived Mesenchymal Stem Cells Loaded on Allograft with Platelet-rich Plasma in Maxillary Sinus Augmentation

Protocol summary

Summary

This study aims to assess the effectiveness of mesenchymal stem cells with allografts and platelet rich fibrin (PRF) in maxillary sinus bone augmentation.This study includes 20 patients with less than 5 mm bone height between alveolar crest and sinus membrane. The samples are randomly allocated (with use of blocks) to two groups of test and control with 10 patients and will receive the surgery at Department of Oral and Maxillofacial Surgery at Shahid Beheshti University of Medical Sciences. In the test group, buccal fat pad derived stem cells (BFPSCs) is harvested from buccal fat pad tissue of the patients. In the test group the patients receive a combination of PRF and freeze dried bone allograft (FDBA) (SureOss, Hansbiomed, Korea) loaded with BFPSCs. The control group receives FDBA (without any cells)+PRF. In all the groups the combination is placed over the maxillary sinus membrane. The results will be evaluated by cone beam computed tomography (CBCT) and hematoxylin and eosin staining in 6 months.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016040427184N2**
Registration date: **2016-07-13, 1395/04/23**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2016-07-13, 1395/04/23

Registrant information

Name

Pantea Nazeman

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 2241 3897

Email address

pnazeman@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Research Institute of Dental Sciences at Shahid Beheshti University of Medical Sciences

Expected recruitment start date

2016-01-01, 1394/10/11

Expected recruitment end date

2016-08-01, 1395/05/11

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Buccal Fat Pad Derived Mesenchymal Stem Cells Loaded on Allograft with Platelet-rich Plasma in Maxillary Sinus Augmentation

Public title

Effect of Buccal Fat Pad Derived Stem Cells in Maxillary Sinus Augmentation

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria: Patients with posterior maxillary edentulism; pneumatized sinus; less than 5mm bone height between the alveolar crest and sinus membrane Exclusion Criteria:Smoking; history of malignancy; radiation; chemotherapy; pregnancy; systemic diseases contradicting dental and surgical treatments; conditions

or drugs affecting bone remodeling or bone metabolism and connective tissue; allergy to collagen

Age
From **18 years** old to **139 years** old

Gender
Both

Phase
1

Groups that have been masked
No information

Sample size
Target sample size: **20**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features
Randomization was performed by randomization blocks

Secondary Ids

1

Registry name
clinicaltrials.gov

Secondary trial Id
NCT02745379

Registration date
2016-04-18, 1395/01/30

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committe at Shahid Beheshti University of Medical Sciences

Street address
Shahid Beheshti University of Medical Sciences, Daneshju blvd, Velenjak

City
Tehran

Postal code
-

Approval date
2013-09-23, 1392/07/01

Ethics committee reference number
Ir.sbmu.rids.rec.1392.9212

Health conditions studied

1

Description of health condition studied
Maxillary bone deficiency

ICD-10 code
-

ICD-10 code description
-

Primary outcomes

1

Description
Amount of regenerated bone

Timepoint
Before the surgery and 6 months after the surgery

Method of measurement
Cone beam computed tomography and histology (microscopic evaluation)

Secondary outcomes

1

Description
-

Timepoint
-

Method of measurement
-

Intervention groups

1

Description
Intervention group: The group receives a combination of FDBA+ BFPSC and PRF for sinus augmentation

Category
Treatment - Surgery

2

Description
Control group: The group receives a combination of FDBA (lacking any cells) and PRF for sinus augmentation

Category
Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center
Department of Oral and Maxillofacial Surgery at Shahid Beheshti University of Medical Sciences

Full name of responsible person
Dr. Arash Khojasteh

Street address
Department of Oral and Maxillofacial Surgery, School of Dentistry,Shahid Beheshti University of Medical Sciences, Daneshju blvd,Velenjak

City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Research Institute of Dental Sciences
Full name of responsible person
Dr. Mohammad Reza Safavi
Street address
5th flour, School of Dentistry,Shahid Beheshti University of Medical Sciences, Daneshju blvd, Velenjak
City
Tehran
Grant name
-
Grant code / Reference number
-
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Research Institute of Dental Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
Name of organization / entity
School of Advanced Technologies in Medicine
Full name of responsible person
Dr. Arash Khojasteh
Position
Dean/ Associate professor of Oral and Maxillofacial Surgery
Other areas of specialty/work
Street address
School of Advanced Technologies in Medicine, Taleghani Hospital, Arabi st, Daneshju blvd
City
Tehran
Postal code
Phone
+98 21 2243 9847
Fax
-
Email
arashkhojasteh@yahoo.com
Web page address
www.omfsresearch.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
School of Advanced Technologies in Medicine
Full name of responsible person
Dr. Arash Khojasteh
Position
Dean/ Associate professor of Oral and Maxillofacial Surgery
Other areas of specialty/work
Street address
School of Advanced Technologies in Medicine, Taleghani Hospital, Arabi st,Daneshju blvd, Velenjak
City
Tehran
Postal code
-
Phone
+98 21 2243 9847
Fax
-
Email
arashkhojasteh@yahoo.com
Web page address
www.omfsresearch.com

Person responsible for updating data

Contact
Name of organization / entity
Dental Research Center, Research Institute of Dental Sciences, Shahid Beheshti University of Medical
Full name of responsible person
Pantea Nazeman
Position
DDS, Research fellow
Other areas of specialty/work
Street address
Dental Research Center, Research Institute of Dental Sciences, School of Dentistry,Shahid Beheshti University of Medical Sciences, Daneshju blvd, Velenjak
City
Tehran
Postal code
-
Phone
+98 21 2241 3897
Fax
+98 21 2241 3897
Email
pnazeman@yahoo.com
Web page address
-

Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty