

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 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

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Iran (Islamic Republic of)

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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 committee 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.sbmurids.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 FDDBA+ BFPSC and PRF for sinus augmentation

Category

Treatment - Surgery

2

Description

Control group: The group receives a combination of FDDBA (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

Web page address
www.omfsresearch.com

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 floor, School of Dentistry, Shahid Beheshti
University of Medical Sciences, Daneshju blvd,
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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

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
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Position
Dean/ Associate professor of Oral and Maxillofacial
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Other areas of specialty/work

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Person responsible for updating data

Contact

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Pantea Nazeman

Position
DDS, Research fellow

Other areas of specialty/work

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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