

Clinical Trial Protocol

Iranian Registry of Clinical Trials

24 Jul 2026

The Effect of Buccal Fat Pad Derived Mesenchymal Stem Cells Loaded on Allograft and Platelet-rich Plasma in Posterior Mandible Augmentation

Protocol summary

Summary

This study aims to assess the effectiveness of mesenchymal stem cells with allografts and PRF in reconstruction of mandible atrophy. This study includes 20 patients with less than 8 mm bone height in posterior mandible. The samples are randomly (by blocks) allocated to two groups of test and control with 10 patients and receive the surgery at Department of Oral and Maxillofacial Surgery at Shahid Beheshti University of Medical Sciences. In the test groups, 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 platelet rich fibrin (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 are placed between the recipient site and the block graft obtained from lateral ramus. The amount of the regenerated bone 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: **IRCT2016040227184N1**

Registration date: **2016-06-13, 1395/03/24**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-06-13, 1395/03/24

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

The Effect of Buccal Fat Pad Derived Mesenchymal Stem Cells Loaded on Allograft and Platelet-rich Plasma in Posterior Mandible Augmentation

Public title

Buccal Fat Pad Derived Stem Cells With Cortical Tenting in Posterior Mandible Reconstruction

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria: patients with posterior mandible edentulism and atrophic bone with less than 4mm bone width at bone crest or less than 8 mm bone height (considering 2-3 mm distance to anatomic structures like CEJ and adjacent tooth) 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

Age

From **18 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 is performed by using blocks

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee at Shahid Beheshti University of Medical Sciences

Street address

Daneshju blvd, Velenjak

City

Tehran

Postal code

Approval date

2013-09-23, 1392/07/01

Ethics committee reference number

lr.sbm.u.ri.ds.rec.1392.9217

Health conditions studied

1

Description of health condition studied

bone atrophy in posterior mandible

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

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The combination of BFPSC+FDBA+PRF is utilized in cortical tenting technique with block graft obtained from lateral ramus for posterior mandible augmentation procedure.

Category

Treatment - Surgery

2

Description

Control group: The combination of FDBA+PRF is utilized in cortical tenting technique with block graft obtained from lateral ramus for posterior mandible augmentation procedure

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

City

tehrna

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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

Full name of responsible person

Dr. Mohammad Reza Safavi

Street address

5th floor, School of Dentistry, Shahid Beheshti
University of Medical Sciences, Velenjak, Daneshju
blvd

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, Shahid Beheshti
University of Medical 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
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Other areas of specialty/work

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Position

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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