Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Clinical and histologic comparision of alveolar ridge preservation following tooth extraction using DFDBA & Bio – oss

Protocol summary

Summary

Objectives: Clinical & histologic evaluation of alveolar bone preservation in extraction sockets using two different graft materials. Single rooted teeth with buccal plate dehiscence more than 2mm or thickness less than 1mm will be included in the study. Patients must not have any systemic disease and not to take any medication that interferes with bone healing response (like diabetes, autoimmune dysfunction, prolonged corticosteroids therapy or chemotherapy). Twenty extraction sockets in twenty patients will be divided into 2 treatment groups randomly; 10 sockets will be augmented with DBBM and collagen membrane, in other 10 sockets DFDBA and collagen membrane will be applied. Horizontal and vertical ridge dimensional changes will be assessed at baseline and after 4-6 months at the time of implant placement. For histological and histomorphometrical analysis, bone samples will be harvested from the augmented sites with the trephine during implant surgery.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013080414270N1**
Registration date: **2014-05-18, 1393/02/28**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2014-05-18, 1393/02/28

Registrant information

Name

Maryam Babaei

Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Presidents Assistant for Science and Technology

Expected recruitment start date

2014-01-21, 1392/11/01

Expected recruitment end date

2014-06-10, 1393/03/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical and histologic comparision of alveolar ridge preservation following tooth extraction using DFDBA & Bio – oss

Public title

Clinical and histologic comparision of alveolar ridge preservation following tooth extraction using DFDBA & Bio – oss

Purpose

Treatment

Inclusion/Exclusion criteria

Patients must not have any systemic disease and should not take any medication that interferes with bone healing response (like diabetes, autoimmune dysfunction, prolonged corticosteroids therapy or chemotherapy). Also, smokers and those who are allergic

to any material uses in this study will be excluded from the study. Only single rooted teeth with buccal plate dehiscence more than 2mm or thickness less than 1mm will be included in the study. In cases with abcess formation, systemic antibiotic including amoxicillin and metronidazole will be given one week prior to extraction.

Age
No age limit

Gender
Both

Phase
2

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

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Dental School of Shahed

Street address
Italia Avn, Keshavarz Blv,Tehran, Iran

City
Tehran

Postal code

Approval date
2014-01-25, 1392/11/05

Ethics committee reference number
191696/41

Health conditions studied

1

Description of health condition studied
Dental socket

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Bucolingual ridge width

Timepoint
In first surgery and 4-6 months after the first surgery

Method of measurement
Coronal border distance from of buccal aspect to the coronal border of the lingual/palatal aspect of the alveolus or ridge at midpoint(with caliper to the nearest tenth of millimeter; 2)

2

Description
Alveolar ridge height

Timepoint
In first surgery and 4-6 months after the first surgery

Method of measurement
The distance between the most coronal point of buccal side of the socket or ridge and the most apical end of the stent at the place of its notch, and similar measurement at lingual/palatal aspect(Michigan-O- probe with William marking was used)

3

Description
Bone formation

Timepoint
4-6 months after the first surgery

Method of measurement
With image analysis software (percent)

4

Description
Type of bone

Timepoint
4 months after the first surgery

Method of measurement
Optic microscopy

5

Description
Residual material

Timepoint
4 months after the first surgery

Method of measurement
Optic microscopy

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: will be grafted with 0.5 cc demineralized freeze-dried bone allograft

(CenoBone;Tissue Regeneration Corporation, Kish Island, Iranparticle size was 150- 2000 micron),and Collagen membrane (Bio-gide; Geistlich Pharma) will be trimmed and placed over the grafted socket and alveolar bone.

Category

Treatment - Drugs

2

Description

Control group: will be grafted with (Bio-Oss; Geistlich Pharma, particle size 0.5-1 mm),and Collagen membrane (Bio-gide; Geistlich Pharma) will be trimmed and placed over the grafted socket and alveolar bone.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Dental school of Shahed

Full name of responsible person

Street address

Italia Avn, Keshavarz Blv,Tehran, Iran

City

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

President Scientific and Research Assistant

Full name of responsible person

Dr. Ali Vatani

Street address

No.162, South Nejatollahi Av-Tehran

City

Tehran

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

President Scientific and Research Assistant

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

Dental School of Shahed University

Full name of responsible person

Rokhsareh Sadeghi

Position

Assistant professor

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