Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Comparison of histological and radiological effect of FDBA with and without autogenous bone graft with collagen membrane in horizontal augmentation of alveolar bone

Protocol summary

Study aim

Histological and radiological comparison of FDBA with and without autogenous bone graft and collagen membrane for horizontal augmentation of alveolar bone

Design

A randomized controlled clinical trial, parallel groups, single blind, Intervention group: Using of FDBA plus autogenous bone to augment alveolar ridge horizontally Control group: Using FDBA alone

Settings and conduct

This study will be done in Kerman Dental School. After flap elevation, in intervention group FDBA plus autogenous bone and collagen membrane and in control group, FDBA and collagen membrane will be used and then flap will be sutured. Two clinicians who are calibrated will perform the radiographic measurements. A code will be given to each radiography for blindness. A pathologist will assess the slides. A code will be given to each slide for blindness

Participants/Inclusion and exclusion criteria

Patients of Kerman University of Medical Sciences. Inclusion criteria: need to horizontal augmentation of alvolar bone for implant (edentulous ridge width: 2/5 - 4 mm and in B-W group) Exclusion criteria: contraindications for implant treatment (use of more than 10 cigarettes per day pregnancy; non controlled periodontal diseases; use of bisphosphonate and corticosteroid; chemotherapy and radiotherapy; systematic diseases for example: non controlled diabetes; osteoporosis and immune deficiency)

Intervention groups

Intervention group: Using of FDBA plus autogenous bone to augment alveolar ridge horizontally Control group: Using FDBA alone

Main outcome variables

Width of alveolar ridge

General information

Reason for update

sample size increased to 42 patients

Acronym

IRCT registration information

IRCT registration number: **IRCT201109165305N3**
Registration date: **2017-06-25, 1396/04/04**
Registration timing: **registered_while_recruiting**

Last update: **2020-03-31, 1399/01/12**
Update count: **1**

Registration date

2017-06-25, 1396/04/04

Registrant information

Name

Mohammad Mohammadi

Name of organization / entity

Kerman Dental School

Country

Iran (Islamic Republic of)

Phone

+98 34 1211 9021

Email address

m_mohammadi@kmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Kerman dental and oral diseases research, vice chancellor for research, Kerman university of medical sciences

Expected recruitment start date

2017-01-20, 1395/11/01

Expected recruitment end date

2017-04-21, 1396/02/01

Actual recruitment start date

2017-05-12, 1396/02/22

Actual recruitment end date

2018-01-07, 1396/10/17

Trial completion date

2018-04-06, 1397/01/17

Scientific title

Comparison of histological and radiological effect of FDBA with and without autogenous bone graft with collagen membrane in horizontal augmentation of alveolar bone

Public title

Comparison of tow different bone grafts for horizontal graft of alveolar bone

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

need to horizontal augmentation of alvolar bone for implant treatment (edentulous ridge width: 2/5 - 4 mm)

Exclusion criteria:

use of more than 10 cigarettes per day pregnancy non controlled periodontal diseases use of bisphosphonate and corticosteroid chemotherapy and radiotherapy systematic diseases for example: non controlled diabetes; osteoporosis and immune deficiency

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: **42**

Actual sample size reached: **42**

Randomization (investigator's opinion)

Randomized

Randomization description

minimization ; At the beginning, participants will be distributed in two groups with throwing coin, then researcher select and distribute the participants in regard to the main inclusion criteria and the sex to balance the groups

Blinding (investigator's opinion)

Single blinded

Blinding description

All radiographic measurements will be done by two clinicians who will be calibrated. Demographic information for each radiography will be deleted and a code was given to each of them. Pathologic assessment will be performed by a pathologist with giving code to each prepared slide.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of kerman medical sciences university

Street address

Tahmasebabad crossroads, researches center

City

Kerman

Province

Kerman

Postal code

7618759689

Approval date

2017-05-03, 1396/02/13

Ethics committee reference number

IR.KMU.REC.1396.1098

Health conditions studied

1

Description of health condition studied

Bone loss

ICD-10 code

M85.8

ICD-10 code description

Other specified disorders of bone density and structure

Primary outcomes

1

Description

Horizontal dimension of alveolar ridge

Timepoint

6 month after insert the implants

Method of measurement

By CBCT

Secondary outcomes

1

Description

Histology of new formed bone

Timepoint

6 months after insert the implants

Method of measurement

Observation with optical microscope

Intervention groups

1

Description
Intervention: Bone graft surgery of alveolar ridge with freezed dried bone allograft {1000-2000 microns granules (Kish tissue regeneration, Kish, Iran) and autogenous bone graft from ramus or chin of patient' own, with 1:1 proportion.
Category
Treatment - Surgery

2

Description
Control: Bone graft surgery of alveolar ridge with freezed dried bone allograft {1000-2000 microns granules (Kish tissue regeneration, Kish, Iran) alone.
Category
Treatment - Surgery

Recruitment centers

1

Recruitment center
Name of recruitment center
Periodontics Dept.,kerman Dental School
Full name of responsible person
Dr. Mohammad Mohammadi
Street address
Shafa street, Dental school
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor for Research, Kerman University of Medical Science
Full name of responsible person
Dr. Pardakhti
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Tahmasbabad Crossroads
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Web page address
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice Chancellor for Research, Kerman University of Medical Science
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
Periodontics Department, kerman dental school
Full name of responsible person
Dr. Mohammad Mohammadi
Position
Assistant professor/Periodontology
Latest degree
Specialist
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Not applicable
Data Dictionary
No - There is not a plan to make this available
Title and more details about the data/document
Data file
When the data will become available and for how long
2020-2021
To whom data/document is available
Academic persons
Under which criteria data/document could be used
No special access criteria
From where data/document is obtainable
E-mail:mmohammadi28@yhoo.com
What processes are involved for a request to access data/document
There are not details
Comments