

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

06 Jul 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 alveolar 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

#### City

Kerman

#### Province

Kerman

#### Postal code

7618759689

#### Phone

+98 34 3211 9021

#### Email

mmohammadi28@yahoo.com

## 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

#### Street address

Tahmasbabad Crossroads

#### City

kerman

#### Province

Kerman

#### Postal code

7618756689

#### Phone

+98 34 3211 9021

#### Email

abpardakhty@kmu.ac.ir

#### 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

#### Other areas of specialty/work

Dentistry

#### Street address

Shafa street, Dental School

#### City

kerman

#### Province

Kerman

#### Postal code

7618759689

#### Phone

+98 34 3211 9021

#### Fax

#### Email

mmohammadi28@yahoo.com

#### Web page address

## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

Kerman dental school

#### Full name of responsible person

Dr.Mohammad Mohammadi

#### Position

Assistant professor/periodontology

#### Latest degree

Specialist  
**Other areas of specialty/work**  
Dentistry  
**Street address**  
Shafa street  
**City**  
Kerman  
**Province**  
Kerman  
**Postal code**  
7618759689  
**Phone**  
+98 34 3211 9021  
**Fax**  
**Email**  
mmohammadi28@yahoo.com  
**Web page address**

## Person responsible for updating data

**Contact**  
**Name of organization / entity**  
Kerman dental school  
**Full name of responsible person**  
Dr. Mohammad Mohammadi  
**Position**  
Assistant professor/periodontology  
**Latest degree**  
Specialist  
**Other areas of specialty/work**  
**Street address**  
Shafa street  
**City**  
Kerman  
**Province**  
Kerman  
**Postal code**  
7618759689

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mmohammadi28@yahoo.com  
**Web page address**

## 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