

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Radiological and histological evaluation of collagen membrane fixation with tack and suturing, and suturing alone in horizontal alveolar ridge augmentation: A Randomized Clinical Trial

#### Protocol summary

##### Study aim

Histological and radiological comparison of collagen membrane fixation with tack and suturing, and suturing alone in horizontal alveolar ridge augmentation.

##### Design

This study is a parallel, single-blind randomized controlled clinical trial that will enroll 40 patients. The patients will be selected by non-probable simple random sampling (available sample). The samples will be randomly divided into two groups; membrane fixation with tack and suturing and membrane fixation with suturing alone.

##### Settings and conduct

The study population are patients who needed horizontal bone augmentation for implant treatment and referred to the KMU Dental School. The study will be performed as a single blind study. Preoperative measurements include measuring the width of the ridge at 0, 2, 4 and 6 mm distances from the Crest through CBCT. 6 months after bone augmentation, the ridge width will be reassessed at same areas as previously measured and compared with preoperative dimensions. Histologic specimens from both groups will be compared in terms of mineralized tissue by light microscopy. All radiographical and histological measurements will be done by clinicians who are blind to the study groups.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: need to horizontal augmentation of alveolar bone for implant (edentulous ridge width: 2/5 - 4 mm and in B-W group). Plaque index and bleeding index less than 20 percent. 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: uncontrolled diabetes and immune deficiency)

##### Intervention groups

Group 1: collagen membrane fixation with tack and suturing  
Group 2: collagen membrane fixation with suturing alone

##### Main outcome variables

width of the ridge

#### General information

##### Reason for update

This study is prospective, but it is registered retrospective, please check it. The recruitment start date was 02/04/2020 and the recruitment end date was 05/11/2021

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20101204005305N19**

Registration date: **2020-03-28, 1399/01/09**

Registration timing: **prospective**

Last update: **2023-09-01, 1402/06/10**

Update count: **1**

##### Registration date

2020-03-28, 1399/01/09

##### 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

**Expected recruitment start date**

2019-09-11, 1398/06/20

**Expected recruitment end date**

2019-11-21, 1398/08/30

**Actual recruitment start date**

2020-04-02, 1399/01/14

**Actual recruitment end date**

2021-11-05, 1400/08/14

**Trial completion date**

2021-12-15, 1400/09/24

**Scientific title**

Radiological and histological evaluation of collagen membrane fixation with tack and suturing, and suturing alone in horizontal alveolar ridge augmentation: A Randomized Clinical Trial

**Public title**

evaluation of collagen membrane fixation with tack and suturing, and suturing alone in alveolar ridge augmentation

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

need to horizontal augmentation of alveolar bone for implant edentulous ridge width: 2/5-4 mm plaque index and bleeding index less than 20 percent.

**Exclusion criteria:**

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

**Age**

No age limit

**Gender**

Both

**Phase**

4

**Groups that have been masked**

- Outcome assessor

**Sample size**

Target sample size: **40**

Actual sample size reached: **44**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Randomization will be done using a coin toss and participants will be divided into intervention and control groups.

**Blinding (investigator's opinion)**

Single blinded

**Blinding description**

Two clinicians who are calibrated and blind to the study will perform all radiographic measurements. The demographic data of all radiographies will be removed and a code will be given to each radiography. A pathologist who is blind to the study will assess the prepared slides. For blindness, a code will be given to

each slides.

**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**

Tahmasbabad Crossover, Researches Center

**City**

Kerman

**Province**

Kerman

**Postal code**

7618759689

**Approval date**

2019-08-25, 1398/06/03

**Ethics committee reference number**

IR.KMU.REC.1398.250

**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**

Alveolar Ridge Width

**Timepoint**

6 month After bone augmentation

**Method of measurement**

By CBCT

**Secondary outcomes****1****Description**

Histology of new formed bone

**Timepoint**

6 months after alveolar ridge augmentation

**Method of measurement**

Observation with optical microscope

**Intervention groups**

**1**

**Description**

Intervention group: collagen membrane fixation with tack and suturing after flap preparation. FDBA bone graft (Kish tissue replicator, Kish, Iran) placed in the surgical site then membrane (Kish tissue Corporation, Kish, Iran) stabilize with Vicryl suture (supa, Tehran, Iran) and tack. Soft tissue closure performs with nylon suture (supa, Tehran, Iran). Six months after the procedure, the implants will be inserted during the second surgery.

**Category**

Treatment - Surgery

**2**

**Description**

Control group: collagen membrane fixation with suturing alone after flap preparation. FDBA bone graft (Kish tissue replicator, Kish, Iran) placed in the surgical site then membrane (Kish tissue Corporation, Kish, Iran) stabilize with Vicryl suture (supa, Tehran, Iran). Soft tissue closure performs with nylon suture (supa, Tehran, Iran). Six months after the procedure, the implants will be inserted during the second surgery.

**Category**

Treatment - Surgery

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Periodontics Department, Kerman Dental School

**Full name of responsible person**

Dr. Mohammad Mohammadi

**Street address**

Shafa street, Dental school

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**Phone**

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**Email**

mmohammadi28@yahoo.com

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Kerman University of Medical Sciences

**Full name of responsible person**

Dr. Hashemi pour

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Kosar 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**

Kerman University of Medical Sciences

**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**

Kerman University of Medical Sciences

**Full name of responsible person**

mohammad mohammadi

**Position**

Assistant Professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Dentistry

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Kerman University of Medical Sciences

**Full name of responsible person**

Dr. Mohammad Mohammadi

**Position**

Assistant Professor

**Latest degree**

Specialist

**Other areas of specialty/work**

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**Latest degree**

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**Other areas of specialty/work**

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be 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**

No - There is not a plan to make this available

**Analytic Code**

No - There is not a plan to make this available

**Data Dictionary**

No - There is not a plan to make this available

## Person responsible for updating data

### Contact

**Name of organization / entity**

Kerman University of Medical Sciences

**Full name of responsible person**

Dr. Mohammad Mohammadi

**Position**