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 will be done by clinicians who are blind to the study groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria: need to horizontal augmentation of alvolar 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)
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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 alvolar 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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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

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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

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Position
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Latest degree
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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