Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Histomorphometrical and radiological comparison of mineralized allogeneic bone graft with or without L-PRF in the reconstruction of horizontal alveolar ridge defects in a randomized controlled clinical trial.

Protocol summary

Study aim
histomorphometrical and radiological comparison of mineralized allogeneic bone graft with or without iPRF in the reconstruction of horizontal alveolar ridge defects

Design
A double-blind randomized clinical trial on 40 patients with a control group and parallel groups. Randomization will be done with minimization method.

Settings and conduct
Kerman university of medical science; faculty of dentistry

Participants/Inclusion and exclusion criteria
The study population includes patients who refer to the School of Dentistry of Kerman University of Medical Sciences. These patients have a B-W edentulous ridge (width 2.5-4 mm) and need horizontal bone aggregation to perform implant treatment. According to similar studies and the limited number of patients who meet the inclusion criteria, the sample size is 20 patients who are divided into two groups of test (using FDBA and iPRF) and control (using FDBA).

Intervention groups
Intervention group: In this group, FDBA and iPRF are used in the reconstruction of horizontal ridge defects.
Control group: In this group, FDBA alone is used to regenerate these lesions.

Main outcome variables
Ridge width change in CBCT view, inflammatory markers in histological view

General information

Reason for update
Increase the sample size

Acronym

IRCT registration information
IRCT registration number: **IRCT20101204005305N20**
Registration date: **2022-02-16, 1400/11/27**
Registration timing: **prospective**

Last update: **2022-11-23, 1401/09/02**
Update count: **2**

Registration date
2022-02-16, 1400/11/27

Registrant information

Name
Mohammad Mohammadi

Name of organization / entity
Kerman Dental School

Country
Iran (Islamic Republic of)

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+98 34 1211 9021

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-10-23, 1400/08/01

Expected recruitment end date
2022-04-19, 1401/01/30

Actual recruitment start date
2022-02-20, 1400/12/01

Actual recruitment end date
2022-09-21, 1401/06/30

Trial completion date
empty

Scientific title
Histomorphometrical and radiological comparison of mineralized allogeneic bone graft with or without L-PRF in the reconstruction of horizontal alveolar ridge defects in a randomized controlled clinical trial.

Public title
Comparison of two methods using mineralized allogeneic bone graft with or without iPRF in the reconstruction of horizontal alveolar ridge defects.
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 Uncontrolled periodontal disease 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

- Participant
- Outcome assessor
- Data analyser

Sample size
Target sample size: **20**
Actual sample size reached: **41**
Randomization (investigator's opinion)
Randomized
Randomization description
Randomization will be done with the minimization method. Randomization of 10 to 20 percent of the samples will be done in a simple way by tossing a coin, and then the participants will be divided into two intervention groups and control groups based on their gender in order to homogenize the groups.
Blinding (investigator's opinion)
Double 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 university of medical science
Street address
Tahmasebabad crossroads, researches center
City
Kerman
Province
Kerman
Postal code
7618759689
Approval date
2021-09-06, 1400/06/15
Ethics committee reference number
IR.KMU.REC.1400.335

Health conditions studied

1

Description of health condition studied
Edentulous ridge width
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Horizontal edentulous ridge width
Timepoint
Measurement of edentulous ridge width by CT scan of the patient at the beginning of the study and 6 months after reconstructive surgery
Method of measurement
Bone width measurement from CBCT radiograph

Secondary outcomes

empty

Intervention groups

1

Description
Control group: First a mid-crystal incision is made and then vertical release incisions with a gap tooth on each side to increase access. The flap is removed in full-thikness. Decoration is done. From Freeze Dried Bone Allogrft 0 granules2000-1000 microns. Kish texture replicator, Kish, Iran) is used. The bone marrow is moistened with sterile saline solution before use. After placement of the target area, it is completely covered by absorbable collagen membrane (thickness 0.4 to 0.6 microns. Kish tissue replicator, Kish, Iran). The membranes are fixed on the membranes by absorbable vicryl sutures (supa, Tehran, Iran) using the horizontal

scrubber technique. Soft tissue closure is initially done with Supa, Iran (Supalon, 5-0) nylon sutures with 3 techniques: Horizontal mattress, interrupted and crisscross. 6 months after the agglomeration process, the implants are placed during the second surgery.

Category

Treatment - Surgery

2

Description

Intervention group: First, blood is taken from the patient's cephalic vein and centrifugation is performed on it to inject platelet rich fibrin. Then, in the operation stage, a mid-crystal incision is made and then the vertical releasing incisions are struck with a gap tooth on each side to increase. The flap is removed in full-thikness. Decoration is done. From Freeze Dried Bone Allogrft 0 granules2000-1000 microns. Kish texture replicator, Kish, Iran) is used with iPRF. The affected bone is moistened with sterile saline solution before use. After placing the desired area, it is completely covered by an absorbable collagen membrane (thickness 0.4 to 0.6 microns. Kish, Kish, Iran) tissue replicator. The membranes are fixed on the membranes by absorbable vicryl sutures (supa, Tehran, Iran) using the horizontal scrubber technique. The closure of the soft tissue is initially done with Supalon, Iran (Supalon 5-0) nylon sutures and with 3 horizontal mattress techniques, cut and crossed. 6 months after the agglomeration process, the implants are placed during the second operation.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Periodontics Department, kerman dental school

Full name of responsible person

Mohammad Mohammadi

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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/Periodontology

Latest degree

Specialist

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

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Full name of responsible person
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Position
Assistant professor/periodontology

Latest degree
Specialist

Other areas of specialty/work
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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
Yes - There is 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
Part of the data is shared after the people are made unrecognizable.

When the data will become available and for how long
2023-2024

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