

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 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)

Phone

+98 34 1211 9021

Email address

m_mohammadi@kmu.ac.ir

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 alveolar 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-thickness. Decoration is done. From Freeze Dried Bone Allograft 0 granules 2000-1000 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 (supra, 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-thickness. Decoration is done. From Freeze Dried Bone Allograft 0 granules 2000-1000 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

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

Kerman University of Medical Sciences

Full name of responsible person

Dr. Abbas Pardakhti

Street address

Tahmasbabad Crossroads

City

Kerman

Province

Kerman

Postal code

7618756689

Phone

+98 34 3211 9021

Email

abpardakhty@kmu.ac.ir

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

Dentistry

Street address

Shafa street, Dental School

City

kerman

Province

Kerman

Postal code

7618759689

Phone

+98 34 3211 9021

Email

mmohammadi28@yahoo.com

Person responsible for scientific 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

Dentistry

Street address

Shafa street

City

Kerman

Province

Kerman

Postal code

7618759689

Phone

+98 34 3211 9021

Email

mmohammadi28@yahoo.com

Person responsible for updating data

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

Street address

Shafa street

City

Kerman

Province

Kerman

Postal code

7618759689

Phone

+98 34 3211 9021

Email

mmohammadi28@yahoo.com

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