Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The comparison of Alloderm with platelet rich fibrin(PRF) Vs free gingival grafts Vs Alloderm to increase the width of keratinized tissue around dental implants : a randomised controlled trial

Protocol summary

Study aim
Determining the effect of using platelet rich fibrin(PRF) together with Aloderm versus Aloderm alone and free gingival grafts(fgg) on increasing the amount of keratinized risks around the implant.

Design
The current study is designed as a randomized, controlled, double-blind trial

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

Participants/Inclusion and exclusion criteria
1. Older than 18 years. 2. Less than 2 mm Keratinized Tissue at the buccal location of the crest ridge on the implant. 3. The presence of healthy tissue around the implant 4. Plaque index and bleeding index below 20% 5. Good general health. 1. Smokers and alcoholics (more than 10 cigarettes). 2. Patients with systemic diseases that can interfere with recovery. 3. Patients treated with bisphosphonate and patients who have already received jaw radiotherapy. 4. Patients with moderate to severe periodontitis. 5. Pregnant women and nursing mothers.

Intervention groups
group 1: In this group, soft tissue augmentation around the implant is performed by Aloderm alone group 2: In this group, soft tissue augmentation around the implant is performed by Alloderm along with prf group 3: In this group, soft tissue augmentation around the implant is performed by fgg

Main outcome variables
the width of keratinized tissue around dental implants

General information

Reason for update
The abbreviation PRF in the title was mistakenly written as Platelet Rich Plasma, which is actually Fibrin Rich Plasma.

Acronym

IRCT registration information
IRCT registration number: **IRCT20101204005305N22**
Registration date: **2024-11-10, 1403/08/20**
Registration timing: **prospective**

Last update: **2025-08-11, 1404/05/20**
Update count: **1**

Registration date
2024-11-10, 1403/08/20

Registrant information

Name
Mohammad Mohammadi
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2024-12-30, 1403/10/10

Expected recruitment end date
2025-01-30, 1403/11/11

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

The comparison of Alloderm with platelet rich fibrin(PRF) Vs free gingival grafts Vs Alloderm to increase the width of keratinized tissue around dental implants : a randomised controlled trial

Public title

The comparison of platelet-rich-fibrin impregnated alloderm Vs free gingival grafts Vs Alloderm to increase keratinized gingival width around dental implants

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

less than 2mm keratinized gingiva healthy periimplant tissue plaque index and bleeding index less than 20% good overal health

Exclusion criteria:

smokers(more than 10 cigarettes per day) Patients with systemic diseases that can interfere with recovery. Patients treated with bisphosphonates and patients who have previously received jaw radiotherapy. Patients with moderate to severe periodontitis. Pregnant women and nursing mothers.

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **36**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization of patients is done by block randomized method, which is as follows: 3 sequences of 12 letters A’B’C are produced and people are entered into the study in groups of 12, then each sequence is removed from its envelope and people Based on it, they are assigned to study groups

Blinding (investigator's opinion)

Double blinded

Blinding description

The need to increase the width of the attached gingiva in these people was determined by a periodontist who does not know the type of treatment. A clinician that is blind to the study will perform all measurements. Patients in all groups receive surgery, but they are not informed about the surgical technique that is performed. However, care and complications after surgery are comprehensively explained

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

Street address

shafa street dental school

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Postal code

7618759689

Approval date

2024-09-08, 1403/06/18

Ethics committee reference number

IR.KMU.REC.1403.238

Health conditions studied

1

Description of health condition studied

width of keratinized tissue around dental implants

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

width of keratinized tissue around dental implants

Timepoint

Keratinized gingival width is achieved in patients 3 months after surgery

Method of measurement

A periodontal probe is used to measure the distance between the gingival margin and the mucogingival junction.

Secondary outcomes

1

Description

The depth of the vestibule

Timepoint

3 months after surgery

Method of measurement

The distance from the gingival margin to the deepest part of the vestibule

Intervention groups

1

Description

Intervention group: 1- First, ten milliliters of whole

venous blood will be collected in two sterile PRF preparation tubes of ten milliliters.2- The tubes will be inserted into the centrifuge at a speed of 700 rpm for 3 minutes.3- Blood is divided into three layers. A cell-free plasma, a middle section containing a fibrin clot, and a red section containing red blood cells at the bottom of the tube.4- PRF is drawn with a syringe.5- Then Eloderm is prepared in the same way as described in the previous group6- Now Alloderm with PRF will be mixed and fixed with periosteal sutures using 0-5 non-absorbable nylon suture material on the recipient site.

Category

Treatment - Surgery

2

Description

Intervention group:In the ADM group, the acellular dermal matrix (AlloDerm®) will be prepared and applied according to the manufacturer's instructions. In summary:1- The membrane will be hydrated with 50 ml of sterile saline solution for 5 minutes.2- When the protective backing paper is removed, the ADM substance will be transferred to another container containing 50 ml of sterile serum solution and will be left there for 5 minutes.3- Then, the allograft will be cut to a size of one by two centimeters4- It will be fixed on the recipient site with periosteal sutures using 0-5 non-absorbable nylon suture material.

Category

Treatment - Surgery

3

Description

Control group:For the control group:1. Taking a 1 to 2 mm thick FGG from the palate, depending on the amount of tissue in the palate of each patient and with dimensions of 1 x 1.5 cm2. Placement and fixation of FGG on the recipient surface with crossed sutures and non-absorbable sutures (Nylon 5.0, Ethilon®).

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
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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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
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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