Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Radiographic and clinical comparison in 4 methods of filling the buccal gap of immediate dental implants using l-PRF،ePRF،Xenograft and without gap filling a randomized clinical trial

Protocol summary

Study aim

Radiographic and clinical comparison of 4 methods of filling the buccal gap of immediate implants using extended platelet-rich fibrin(e_PRF), leukocyte- and platelet-rich fibrin(l_PRF), xenograft, no gap filling

Design

A randomized clinical trial with a control group and sample concealment, blinding with parallel groups, is being conducted on 48 patients in 4 groups.

Settings and conduct

Patients for immediate implant placement, if they meet the entry criteria, are randomly assigned to each group, consisting of 12 people. Based on the block randomization method, they are divided into 4 groups: Immediate implant and no buccal gap filling Immediate implant and buccal gap filling using xenograft Immediate implant and buccal gap filling using L-PRF Immediate implant and buccal gap filling using e-PRF Blinding is performed during the radiographic data collection stage and the individuals who collect the soft tissue topography scan files and during the statistical data analysis stage.

Participants/Inclusion and exclusion criteria

Inclusion criteria Systemic health and no drug or alcohol addiction Type 1 socket Plaque index less than 20% buccal gap greater than mm2 Exclusion criteria infection, deep probing depth, and initial implant instability Need for simultaneous bone grafting

Intervention groups

The control group does not place any material in the buccal gap. The Xenograft group, Serabone, is packed in the buccal gap. The third group, L-PRF, is placed at a setting of 2700 for 12 minutes.The fourth group, e-PRF, is placed in the buccal gap.after blood collection, centrifugation is performed at 700 for 8 minutes, a layer of Poor Plasma Fibrin is placed in the heater to coagulate proteins and mixed with PRF.

Main outcome variables

Percentage of implant height covered by bone in buccal, measurement of the distance between the external surface of the bone and the implant shoulder

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20251004067496N1**
Registration date: **2026-01-08, 1404/10/18**
Registration timing: **registered_while_recruiting**

Last update: **2026-07-04, 1405/04/13**
Update count: **1**

Registration date

2026-01-08, 1404/10/18

Registrant information

Name

Nazila Lashkarizadeh

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-11-22, 1404/09/01

Expected recruitment end date

2026-03-21, 1405/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Radiographic and clinical comparison in 4 methods of filling the buccal gap of immediate dental implants using l-PRF،ePRF،Xenograft and without gap filling a randomized clinical trial

Public title

Radiographic and clinical comparison of buccal gap filling methods in immediate implants.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Systemically healthy patient Patients who are at least 18 years old The tooth socket must be type 1 (buccal soft tissue and buccal and lingual bone plates must be intact) Non-molar teeth that cannot be maintained Immediate implant placement (achieving initial stability of at least 35Ncm) is possible without moving the flap and there is sufficient intraocclusal space. It is possible to place an implant fixture with a horizontal buccal gap greater than 2 mm. A person with adequate oral hygiene with a plaque index less than or equal to 20 percent

Exclusion criteria:

People who smoke or are addicted to drugs or alcohol People who are pregnant or have systemic diseases such as diabetes, or if they are taking antibiotics or drugs that weaken the immune system such as corticosteroids. Probing depth greater than three millimeters buccally or lingually The need for bone grafting at the same time as implant placement Presence of local or systemic conditions that are contraindications to implant placement

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Care provider
- Outcome assessor
- Data analyser

Sample size

Target sample size: **68**

Randomization (investigator's opinion)

Randomized

Randomization description

Block randomization is performed using software and a sealed envelope tool is used. Blinding is performed during the clinical data collection phase (soft tissue thickness measurement is performed by a dentist who is unaware of the grouping before surgery) and review of scan files and statistical analysis. The person taking the radiographic measurements is also unaware of the study grouping (only after 3 months of surgery is the xenograft group distinguished from the other groups due to the observation of bone particles on the radiograph). The participants in the study are not blinded.

Blinding (investigator's opinion)

Single blinded

Blinding description

during the clinical data collection phase (soft tissue thickness measurement is performed by a dentist who is unaware of the grouping before surgery) and review of scan files and statistical analysis. The person taking the radiographic measurements is also unaware of the study grouping (only after 3 months of surgery is the xenograft group distinguished from the other groups due to the observation of bone particles on the radiograph). The participants in the study are not blinded.

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 Sciences

Street address

Research Ethics Committee, Kerman University of Medical Sciences, Beginning of Haft Bagh Alavi Axis, University of Medical Sciences Campus

City

Kerman

Province

Kerman

Postal code

7616910002

Approval date

2025-11-10, 1404/08/19

Ethics committee reference number

IR.KMU.REC.1404.439

Health conditions studied

1

Description of health condition studied

People with systemic health conditions

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Buccal bone thickness (post-surgery): Linear measurement of the distance between the external surface of the bone and the implant shoulder at distances of 0, 2, 4, and 6 mm from the implant shoulder perpendicular to the long axis of the implant.

Timepoint
At the beginning of the study and 3 months after surgery

Method of measurement
Measurements of the width of the socket in the coronal and apical sections, perpendicular to the longitudinal axis of the socket, are made linearly on the 3D image DIACOM file, by a person who is unaware of the grouping.

2

Description
Implant coverage by bone: Percentage of implant height covered by bone in the buccal areas.

Timepoint
3 months after surgery

Method of measurement
Bone thickness and height (percentage of implant covered by bone both buccally and lingually) are performed linearly on the 3D image dycom file by a person who is unaware of the grouping.

Secondary outcomes

1

Description
Soft tissue thickness

Timepoint
Beginning of the intervention and three months later

Method of measurement
Endo file and gauge

2

Description
Distance of the gingival margin from the edge of the healing abutment

Timepoint
Beginning of the intervention and three months later

Method of measurement
Periodontal probe, parallel to the longitudinal axis of healing

3

Description
Keratinized gingival width

Timepoint
Beginning of the intervention and three months later

Method of measurement
Periodontal probe

4

Description
Soft tissue contour

Timepoint
Before the intervention and three months later

Method of measurement
Preparation of a digital file of the buccal soft tissue contour in format standard tessellation language and superimposition format to examine changes in the soft tissue contour.

Intervention groups

1

Description
Intervention group: In the Xenograft group, cera bone with particle sizes of 150-1000 microns was hydrated in normal saline for 10 minutes and packed in the buccal gap area up to the bone crest area.

Category
Other

2

Description
Intervention group: In the L-PRF group, after blood collection from the brachial artery, it is placed in 2 red 9 ml test tubes in a centrifuge at 2700 rpm for 12 minutes. After this time, the obtained L-PRF is separated from the red blood cells and packed by the special area in the PRF kit to produce L-PRF plug.

Category
Other

3

Description
Intervention grouIn the buccal gap filling e-PRF group, after blood collection from the brachial artery in a 9 ml white test tube, it is centrifuged at 700 rpm for 8 minutes. After that, to prepare e-PRF, first 2 ml of the liquid was obtained. In the test tube, which is PPP (platelet poor plasma), it is aspirated using a 3 ml locking syringe And this syringe is placed in a heater for 10 minutes at 75°C to coagulate the proteins. During this time, the test tubes are placed in the refrigerator to prevent coagulation. After ten minutes, the syringes are removed from the heater and placed in the refrigerator to reach room temperature, and the centrifuge tubes are removed from the refrigerator and their plastic lids are opened and the L-PRF layer and buffy coat are aspirated using a locking syringe. The syringe containing the PPP is coagulated and PRF is connected using the syringe connector, and the contents of the syringe are mixed and injected into the buccal gap and packed up to the gingival margin using a condenser.

Category
Other

4

Description
Control group: In the control group, no material is placed in the buccal gap.
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Dentistry school
Full name of responsible person
Nazila Lashkarizadeh
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Sponsors / Funding sources

1

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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
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
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
There is no further information
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