

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Studying the effect of platelet-rich fibrin (L-PRF) plug on the level of alveolar crest keratinized gingiva in immediate implant placement

Protocol summary

Study aim

Studying the effect of platelet-rich fibrin plug (L-PRF) on the formation of alveolar crest keratinized gingiva in immediate implant placement

Design

clinical trial, With control group, parallel groups, single-blind, randomized, phase 3 on 60 patients. Random Allocation software was used for randomization.

Settings and conduct

The study will be conducted in the special dental clinic of Mazandaran University of Medical Sciences (Toubi Clinic). The implant used in the study will be of Snucone brand, made in Korea, with SLA level, along with two-stage surgery (cover screw closing) and covering the implant with gingiva. For the control group, after placing the implant, no additional step will be performed. In the intervention group, after placing the implant, platelet-rich fibrin (L-PRF) will be placed on it. Blinding with random allocation software The researcher is blind

Participants/Inclusion and exclusion criteria

Inclusion criteria included subjects with systemic health (class 1 according to the ASA classification); colleagues, with good oral hygiene and no acute infection; patients with teeth due to terminal periodontal disease, root fracture, or root resorption indicated for extraction; and patients who wanted to visit again; In addition, patients should not have untreated periodontal disease.

Intervention groups

The implant used in the study will be of Snucone brand, made in Korea, with SLA level, along with two-stage surgery (cover screw closing) and covering the implant with gingiva. For the first group, no additional steps will be taken after placing the implant. In the second group, after placing the implant, platelet-rich fibrin (L-PRF) will be placed on it.

Main outcome variables

Keratinized gingiva width; keratinized gingiva thickness

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221228056958N2**

Registration date: **2024-06-03, 1403/03/14**

Registration timing: **registered_while_recruiting**

Last update: **2024-06-03, 1403/03/14**

Update count: **0**

Registration date

2024-06-03, 1403/03/14

Registrant information

Name

Najmeh Sadat Valed Saravi

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 11 3331 4614

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-02-17, 1402/11/28

Expected recruitment end date

2024-07-20, 1403/04/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Studying the effect of platelet-rich fibrin (L-PRF) plug on the level of alveolar crest keratinized gingiva in immediate implant placement

Public title

Effect of platelet rich fibrin on soft tissue quality after immediate implant placement

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

People with systemic health (class 1 according to the ASA classification) cooperative good oral hygiene and absence of acute infection Patients with teeth indicated for extraction due to terminal periodontal disease, root fracture, or root resorption Patients who were willing to visit again. Patients should not have untreated periodontal disease.

Exclusion criteria:

patients with compromised systemic conditions (ASA 2,3,4,5,6) inadequate oral hygiene and presence of acute infection Patients without teeth indicated for extraction or unwilling for implant treatment Patients unwilling to visit again Patients with untreated periodontal disease Uncooperative

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked

- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: 60

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization method: randomization will be block (blocks of 4) and individually Randomization tool: random allocation software 2 Using the software, codes A and B will be generated, where code A means applying the intervention group and code B means applying the control group for each person. Finally, the codes will be placed in the sealed envelope and the number of each patient will be written on the envelope. After the arrival of each patient, the doctor will open the envelope and apply the intended treatment.

Blinding (investigator's opinion)

Single blinded

Blinding description

In this study, the researcher is unaware of the type of treatment performed on the patient, and this information is kept with the surgeon.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Mazandaran University of Medical Sciences

Street address

Sari, Jouybar three ways, Mazandaran University of Medical Sciences

City

sari

Province

Mazandaran

Postal code

۴۸۱۵۷۳۳۹۷۱

Approval date

2025-02-11, 1403/11/23

Ethics committee reference number

IR.MAZUMS.REC.1402.618

Health conditions studied

1

Description of health condition studied

Lack of keratinized gingiva around the implant

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Keratinized gingiva width

Timepoint

Before tooth extraction, 2 weeks after healing abutment placement

Method of measurement

Using a periodontal probe and the Rolling technique

2

Description

Keratinized gingiva thickness

Timepoint

Before tooth extraction, 2 weeks after healing abutment placement

Method of measurement

Using a Williams periodontal probe that goes into the tissue until it reaches the bone.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The implant used in the study will be of Snucone brand, made in Korea, with SLA level, along with two-stage surgery (cover screw closing) and covering the implant with gingiva. The implant will be placed at the level of the crest or at most 0.5 mm below the corset (if the thickness of the corset is less than 1 mm and there is a possibility of resorption). After placing the implant, it will be placed on it as a platelet and leukocyte-rich fibrin plug (L-PRF). The surgeon will administer platelet and leukocyte-rich fibrin (L-PRF).

Category

Treatment - Surgery

2

Description

Control group: The implant used in the study will be of Snucone brand, made in Korea, with SLA level, along with two-stage surgery (cover screw closing) and covering the implant with gingiva. The implant will be placed at the level of the crest or at most 0.5 mm below the crest (if the thickness of the corset is less than 1 mm and there is a possibility of resorption). In the first group, after placing the implant, an additional step will not be performed, and the flap will be displaced coronally just to avoid exposing the implant.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Tooba Dental Clinic

Full name of responsible person

Dr. Najme Sadat Valed Saravi

Street address

Tooba dental clinic, khazar blvd., sari

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Mazandaran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Dr. Pedram Ebrahim Nezhad

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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

Mazandaran 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

Mazandaran University of Medical Sciences

Full name of responsible person

Dr. Najme Sadat Valed Saravi

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

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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

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Other areas of specialty/work

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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

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available