Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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

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Iran (Islamic Republic of)

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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

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sari

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Mazandaran

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۴۸۱۵۷۳۴۹۷۱

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 thichness

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 corset 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

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Tooba dental clinic, khazar blvd., sari

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Mazandaran 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
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

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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