

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

Comparison effect of Connective Tissue Graft (CTG) and Platelet Rich Fibrin in treatment of gingival recession.

Protocol summary

Study aim

The main aim is to compare the clinical effects of palatal grafting (Connective Tissue Graft) and Platelet Rich Fibrin in root coverage surgery

Design

The study is a double-blind split mouth clinical trial in which the patient and the evaluator in the study are blind.

Settings and conduct

This study will be conducted on patients referred to the Faculty of Dentistry, Islamic Azad University of Medical Sciences, Tehran. The surgery is performed bilaterally in each patient, on one side using fibrin rich in platelets (through centrifugation of the patient's blood) and on the other side, palatal connective tissue is taken.

Participants/Inclusion and exclusion criteria

Non-smoker and non-alcoholic; Systemically healthy; Age over 18 years; O'LEARY Index less than 20 percent; The presence of gingival erosion of Miller class 1 on the buccal surface of two non-adjacent anterior teeth of the upper and lower jaw; The depth of the probe is less than 3 mm; The amount of gingival recession is at least 2 mm; Thin periodontal biotype; The presence of attached gingiva at least 2 mm; Absence of cervical restoration in the treatment areas; No history of root coverage surgery ; No history of trauma

Intervention groups

Control: CTG Test:PRF

Main outcome variables

Pocket probing depth, Clinical attachment level, Recession depth, Gingival thickness, Keratinized Gingival Width, Percentage of root coverage, patient's esthetic score and patient sensitivity score

General information

Reason for update

Acronym

CTG, PRF

IRCT registration information

IRCT registration number: **IRCT20231211060331N1**

Registration date: **2023-12-17, 1402/09/26**

Registration timing: **prospective**

Last update: **2023-12-17, 1402/09/26**

Update count: **0**

Registration date

2023-12-17, 1402/09/26

Registrant information

Name

Mahsa Soleimani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2256 4571

Email address

m.soleimani@iautmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-02-12, 1402/11/23

Expected recruitment end date

2024-06-20, 1403/03/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison effect of Connective Tissue Graft (CTG) and Platelet Rich Fibrin in treatment of gingival recession.

Public title

Comparison effect of Connective Tissue Graft (CTG) and Platelet Rich Fibrin in treatment of gingival recession.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

No systemic disease
Bilateral gingival recession Miller 1
Plaque index less than 20%

Exclusion criteria:

Systemic disease
No existence of bilateral gingival recession Miller 1
Poor oral hygieny

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **13**
More than 1 sample in each individual
Number of samples in each individual: **2**
Bilateral gingival recession

Randomization (investigator's opinion)

Randomized

Randomization description

To reduce selection bias, the priority of treatment on the right and left side and which treatment should be performed on which side of the patient It is done with Random allocation of concealed using SNOSE (Sequentially numbered sealed opaque) envelopes, that is, sealed and numbered envelopes. (Because the envelopes are sealed, Allocational Concealment will also be done at the same time as Randomization itself.) Blocked randomization is not possible in small volumes. Therefore, the order of performing surgery on the right or left side is done by the method of numbered envelopes

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, there is no possibility of blinding the surgeon and only the evaluator during the measurements The studied parameters do not know the method performed on the right and left side (which treatment was performed on which side).

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Tehran Islamic Azad University of Medical Sciences

Street address

9th Neyestan St., Pasdaran St., Tehran

City

Tehran

Province

Tehran

Postal code

1946853314

Approval date

2023-11-25, 1402/09/04

Ethics committee reference number

IR.IAU.DENTAL.REC.1402.108

Health conditions studied

1

Description of health condition studied

Gingival recession

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Pocket Probing Depth

Timepoint

Day 0 & month 3 & 6

Method of measurement

William probe

2

Description

Recession Depth

Timepoint

Day 0 & month 3 & 6

Method of measurement

William probe

3

Description

Width of keratinized gingiva

Timepoint

Day 0 & month 3 & 6

Method of measurement

William probe

4

Description

Root Coverage percent

Timepoint

Day 0 & month 3 & 6

Method of measurement

Formula

5**Description**

Patient Esthetic Score

Timepoint

Day 0 & month 3 & 6

Method of measurement

Visuagal Analog Score

6**Description**

Sensitivity Score

Timepoint

Day 0 & month 3 & 6

Method of measurement

Visual Analog Score

7**Description**

Clinical Attachment Level

Timepoint

Day 0 & month 3 & 6

Method of measurement

William prob

8**Description**

Gingival Thickness

Timepoint

Day 0 & month 3 & 6

Method of measurement

Endodontic Reamer

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: Platelet Rich Fibrin

Category

Treatment - Surgery

2**Description**

Control group: Connective Tissue Graft

Category

Treatment - Surgery

Recruitment centers**1****Recruitment center****Name of recruitment center**

Tehran Islamic Azad University of Medical Sciences

Full name of responsible person

Dr. Mahsa Soleimani

Street address

N.9, 9th Neyestan St., Pasdaran St.

City

Tehran

Province

Tehran

Postal code

1946853314

Phone

+98 21 2256 4571

Email

Int.affairs@tms.iau.ir

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Islamic Azad University

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

Islamic Azad University

Proportion provided by this source

20

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

Islamic Azad University

Full name of responsible person

Mahsa Soleimani

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

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Email

dr.soleimani63@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

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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

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Only data related to results and outcomes will be published.

When the data will become available and for how long

At least 1 month after the end of the study

To whom data/document is available

People with relevant academic education

Under which criteria data/document could be used

Only the data related to the obtained results will be accessible.

From where data/document is obtainable

drsoleimani63@gmail.com

What processes are involved for a request to access data/document

At least 1 week after receiving the email

Comments