

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Aug 2026

Comparison of soft tissue evaluation consequent to platelet rich fibrin(PRF) usage versus connective tissue graft in immediate posterior implants

Protocol summary

Study aim

Evaluation of soft tissue changes consequent to PRF usage in immediate implants for posterior teeth

Design

Two arm parallel group randomized trial with blinded postoperative care and outcome assessment.

Settings and conduct

Patients were selected among clients of Implant Department and Dental Clinic of Mashhad dental university and then were randomized into two groups. The jumping gaps were filled with allograft in both groups. In the test group, we collected 9ml of blood from each patient in order to make PRF membranes (centrifuge at 2700rpm for 12min). We then used the PRF membranes to cover the sockets of posterior immediate implants. In the control group, we used CTG to cover the sockets of posterior immediate implants. Keratinized tissue width was measured at the time of surgery, 1 month and 3 months after surgery. Keratinized tissue thickness was also measured at the time of surgery and 3 months after the surgery.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Agreeable oral hygiene (plaque index under 20%); partial edentulousness in posterior regions of the jaws; adequate bone quantity at the implant site; no need for periodontal surgery adjacent to the implant site; occlusal stability of the dentition. Exclusion criteria: Infection around implant site; history of bleeding disorders or anticoagulant therapy; immunocompromised state and debilitating diseases; severe systemic disease; tobacco use (more than 15 per day); drug addiction or alcoholism

Intervention groups

All patients were treated using the same implant system (implantium, bone level). 1. test: PRF as membrane+ allograft (MBA powder 500-1000µ, regen, Iranian tissue product co) 2. control:

CTG without PRF+ allograft (MBA powder 500-1000µ, regen, Iranian tissue product co)

Main outcome variables

Keratinized tissue width; Keratinized tissue thickness; Membrane type (CTG, PRF)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190723044313N1**

Registration date: **2020-11-20, 1399/08/30**

Registration timing: **retrospective**

Last update: **2020-11-20, 1399/08/30**

Update count: **0**

Registration date

2020-11-20, 1399/08/30

Registrant information

Name

Mounes Jamali

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3868 8114

Email address

jamalim971@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-01-05, 1398/10/15

Expected recruitment end date

2020-07-22, 1399/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of soft tissue evaluation consequent to platelet rich fibrin(PRF) usage versus connective tissue graft in immediate posterior implants

Public title

Evaluation of platelet rich fibrin(PRF) effects on soft tissue changes in immediate implants for posterior teeth

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Good oral hygiene(plaque index under 20%) Partially edentulous on posterior region of jaw Adequate bone quantity at the implant site No need for periodontal surgery adjacent to the implant site Occlusal stability of the dentition

Exclusion criteria:

Infection around implant site History of bleeding disorder or anticoagulant therapy Immunocompromised state and debilitating disease Severe systemic disease Tobacco use (more than 15 per day) Drug addiction or alcoholism

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size

Target sample size: 30

Randomization (investigator's opinion)

Randomized

Randomization description

in our study randomization take place using randomization.com website and random number has inserted in pocket. On the basis of the number in the pocket (even or odd), patients allocate to the test or control group.

Blinding (investigator's opinion)

Double blinded

Blinding description

In the current study, the surgeon and the patients were not able to be blinded due to the intervention including the usage of PRF in one group. Therefore, the assessor and the data analyzers were blinded.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Mashhad University of Medical Sciences

Street address

Vakil abad Blvd, Mashhad dental faculty

City

Mashhad

Province

Razavi Khorasan

Postal code

9177948959

Approval date

2019-12-25, 1398/10/04

Ethics committee reference number

IR.MUMS.DENTISTRY.REC.1398.080

Health conditions studied**1****Description of health condition studied**

periodontal disease

ICD-10 code

K13.22

ICD-10 code description

Minimal keratinized residual ridge mucosa

Primary outcomes**1****Description**

Keratinized gingiva width

Timepoint

Baseline, 1 month and 3 month after surgery

Method of measurement

Periodontal probe

Secondary outcomes**1****Description**

Keratinized gingiva thickness

Timepoint

Baseline and 3 month after surgery

Method of measurement

Periodontal probe

Intervention groups

1

Description

Intervention group: Jumping gap was filled with allograft (MBA powder 500-1000μ, regen, Iranian tissue product co). We collected 9ml of blood from each patient in order to make PRF membranes (centrifuge at 2700rpm for 12 min). We used the PRF membranes to cover the sockets of posterior immediate implants. Keratinized tissue width was measured at the time of surgery, 1month and 3 months after the surgery. Keratinized tissue thickness was measured at the time of surgery and 3 months after the surgery.

Category

Treatment - Surgery

2

Description

Control group: Jumping gap was filled with allograft (MBA powder 500-1000μ, regen, Iranian tissue product co). CTG (harvested from palate) was used to cover the sockets of posterior immediate implants. Keratinized tissue width was measured at the time of surgery, 1month and 3 months after the surgery. Keratinized tissue thickness was measured at the time of surgery and 3 months after the surgery.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Mashhad University of Medical Sciences

Full name of responsible person

Mounes Jamali

Street address

Vakilabad Blvd, Mashhad dental faculty

City

Mashhad

Province

Razavi Khorasan

Postal code

9177948959

Phone

+98 51 3846 0502

Email

jamalim971@mums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Reza Zare Mahmoodabadi

Street address

Vakil abad Blvd, Mashhad dental faculty

City

Mashhad

Province

Razavi Khorasan

Postal code

9177948959

Phone

+98 51 3806 7100

Fax

Email

jamalim971@mums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Mashhad 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

Mashhad University of Medical Sciences

Full name of responsible person

Mounes Jamali

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Dentistry

Street address

Vakil abad Blvd, Mashhad dental faculty

City

Mashhad

Province

Razavi Khorasan

Postal code

9177948959

Phone

+98 51 3806 7257

Email

jamalim971@mums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Mounes Jamali

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Dentistry

Street address

Vakil abad Blvd, Mashhad dental faculty

City

Mashhad

Province

Razavi Khorasan

Postal code

9177948959

Phone

+98 51 3806 7257

Email

jamalim971@mums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Mounes Jamali

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Dentistry

Street address

Vakil abad Blvd, Mashhad dental faculty

City

Mashhad

Province

Razavi Khorasan

Postal code

9177948959

Phone

+98 51 3806 7257

Email

jamalim971@mums.ac.ir

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 more information.

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