Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

A comparative study of the effect of leukocyte and fibrin-rich plasma (L-PRFin soft tissue thickness, tissue healing rate, pain and discomfort after peri-implant treatment in people needing dental implants (split- mouth randomized controlled trial)

Protocol summary

Study aim
Determining the effect of leukocyte and fibrin-rich plasma (L-PRF) in increasing the thickness of soft tissue, tissue healing rate, pain and discomfort after treatment around dental implants.

Design
A clinical trial with a control group, with parallel groups, double-blind, randomized, on 10 patients, to randomize the type of treatment using the block randomization method. It will be used with a block size of 4 (randomization was done with SAS software version 9)

Settings and conduct
Patients referring to the periodontal surgery department of Guilan Faculty of Dentistry who need implant placement in the mandibular premolars will be selected based on the entry criteria. After preparing the osteotomy cavity for implant placement, the samples are randomly placed in 2 groups: 1st control group where no material is placed around the implant, 2nd group L-PRF is placed on the buccal side around the implant under the flap. Then, DENTIS implant is placed in two steps for all samples.This trial will be conducted in a double-blind manner. The evaluator and the analyst of the results will be blinded.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Age 20-60; Partial edentulous patient; The patient index before surgery is less than 25%. Exclusion criteria: Smokers; Pregnant and lactating women; History of radiation therapy and chemotherapy; Patients with active symptoms of infection such as pain, swelling, pus and abscess; Untreated advanced periodontitis; Blood disease and diabetes; Hyperthyroidism; High blood pressure.

Intervention groups
1- control group that no material is placed around the implant, group 2- where L-PRF is placed around the implant on the buccal side under the flap.

Main outcome variables
The thickness of the soft tissue around the implant, pain, the degree of healing of the soft tissue

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20130813014350N5**
Registration date: **2022-10-16, 1401/07/24**
Registration timing: **registered_while_recruiting**

Last update: **2022-10-16, 1401/07/24**
Update count: **0**

Registration date
2022-10-16, 1401/07/24

Registrant information

Name
Bardia Vadiati Saberi
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-09-23, 1401/07/01

Expected recruitment end date
2022-12-22, 1401/10/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
A comparative study of the effect of leukocyte and fibrin-rich plasma (L-PRFin soft tissue thickness, tissue healing rate, pain and discomfort after peri-implant treatment in people needing dental implants (split- mouth randomized controlled trial)

Public title
Investigating growth factors and complications after implant treatment
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Age 20-60 Partial edentulous patient The plaque index before surgery is less than 25%
Exclusion criteria:
smokers Pregnant and lactating women History of radiation therapy and chemotherapy Patients with active symptoms of infection such as pain, swelling, pus and abscess Untreated advanced periodontitis Blood disease and diabetes Hyperthyroidism High blood pressure
Age
From **20 years** old to **60 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **10**
Randomization (investigator's opinion)
Randomized
Randomization description
In order to randomize the type of treatment on the left and right sides of the permuted block randomization method. randomization) with a block size of 4 will be used. Considering that A represents the right side and B represents the left side, the randomization process will be as follows (randomization was done with SAS version 9 software): Seed: 51660630849336 Block sizes: 4 Actual list length: 8 block identifier, block size, sequence within block, treatment • 1, 4, 1, Group B • 1, 4, 2, Group B • 1, 4, 3, Group A • 1, 4, 4, Group A • 2, 4, 1, Group B • 2, 4, 2, Group B • 2, 4, 3, Group A • 2, 4, 4, Group A
Blinding (investigator's opinion)
Double blinded
Blinding description
This trial will be conducted in a double-blind manner. In this category of studies, there is no possibility of blinding the patient due to blood sampling when he is subjected to surgery for the purpose of the experimental group. Therefore, in the present study, the outcome evaluator will not know the type of sample to be evaluated, and also The analyst of the study results will not know about the studied groups.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Guilan University of Medical Sciences
Street address
No. 103, Rose Building, Parvaneh Dead End, Koi Shahid Amini, Ahmadzadeh Blvd., Bostan Mellat
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Approval date
2022-08-21, 1401/05/30
Ethics committee reference number
IR.GUMS.REC.1401.258

Health conditions studied

1

Description of health condition studied
Soft tissue thickness, tissue healing rate, pain and discomfort after treatment around dental implants
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
The thickness of the soft tissue around the implant
Timepoint
Baseline and 6 weeks later
Method of measurement
Measurement by periodontal probe in mm

Secondary outcomes

1

Description
Postoperative pain assessment
Timepoint
during 7 days after surgery (days1,2,3,7)
Method of measurement
Visual analog scale(VAS) index

2

Description
Soft tissue healing rate
Timepoint
Day 7 and day 14 after surgery
Method of measurement
(Landry Index) which includes tissue color, BOP, epithelialization of wound margin, presence of tissue granulation and presence of pus.

Intervention groups

1

Description
This study will be an interventional split-moth study that examines the effect of using L-PRF on the success of dental implants in 1 target group and 1 control group. At the beginning of the plan, the consent form will be completed by the patient. Then, the patient's personal characteristics such as age, gender, medical history and drug use are recorded.(Checklist No. 1) In this study, 10 patients referring to the periodontal surgery department of Gilan Faculty of Dentistry who need to place implants in the mandibular premolars will be selected based on the inclusion criteria.After the external and intraoral examinations, each patient is given full training regarding the control of oral plaque, and if dental plaque is observed, they receive scaling and root planing. Measuring the thickness of the buccal soft tissue by periodontal probe in millimeters. It will be done. On the day of the surgery, the patient will first rinse his mouth with 0.12% chlorhexidine and we will use iodine as an extraoral antiseptic.Local anesthesia (lidocaine HCl 2% with epinephrine 1:100,000) will be injected. Preparation of L-PRF: 9 ml of whole blood is collected from each patient in a plastic tube and immediately centrifuged for 12 minutes at 2700 rpm (or power 400 g at room temperature in a DUO Quattro centrifuge (49 Rue Gioffredo, 06000 Nice, France) will be centrifuged by the relevant technician who is a research associate (resident), and because it takes less time, it is easier to prepare. Then the fibrin clot which is formed in the middle of the tube (exactly between the red blood cells below and the cell-free plasma in the upper part), after the upper plasma is removed, it is separated from the lower blood cells using sterile forceps and scissors and transferred to a sterile compress.After preparing the osteotomy cavity for implant placement, the samples are randomly placed in 2 groups: control group 1, where no material is placed around the implant, group 2, where L-PRF is placed around the implant on the buccal side under the flap. For all samples, the DENTIS implant is placed in two stages. In both groups, full coverage will be done using 0-4 Silk suture thread and in a simple loop. Gelofen was prescribed for patients before surgery and 6 hours after surgery to continue using it if there is pain. The patient is advised to avoid eating hard and sticky foods or using a toothbrush in the surgical area and not to use the removable prosthesis for a week. After a week, the suture is removed. The final restoration will be placed after 3 months. The surgery is performed by a periodontist and the evaluation of the samples is performed by a periodontist who is unaware of the type of samples. Patient follow-up by a research associate (resident) to evaluate clinical parameters at baseline and 6 weeks later to check the thickness of soft tissue around the implant as a primary outcome and to evaluate pain during 7 days after surgery (days 7, 3, 2, 1) and the amount of soft tissue improvement on day 7 and day 14 after surgery will be performed as a secondary outcome. Clinical parameters include soft tissue thickness (measured by periodontal probe in millimeters), patient pain (VAS index), soft tissue improvement (Landry Index) , which includes tissue color, BOP, epithelialization of wound margin, presence of tissue granulation And the presence of pus.
Category
Treatment - Surgery

Recruitment centers

1

Recruitment center
Name of recruitment center
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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
Dental Research Center, Guilan 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
Rasht University of Medical Sciences
Full name of responsible person
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Latest degree
Specialist
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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

Undecided - It is not yet known if there will be 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

Comparison of the effect of leukocyte and fibrin-rich plasma on the change of soft tissue thickness, tissue healing rate, pain and discomfort after peri-implant treatment in people who need dental implants, a split mouth randomized controlled clinical trial. All data can be shared after de-identifying individuals.

When the data will become available and for how long

6-12 months after result publication

To whom data/document is available

Researchers working in academic institutions

Under which criteria data/document could be used

Use in higher level studies such as systematic review studies

From where data/document is obtainable

Bardia@gums.ac.ir

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

Documents for writing a review article (for example, an invitation letter from the desired journal) should be provided

Comments