Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Clinical and Radiographic Evaluation of the Effect of Using Photobiomodulation in Comparison with Platelet-Rich Fibrin on Dental Sockets Healing: A Single-blind Randomized Clinical Trial

Protocol summary

Study aim
Comparison of the Effect of Photobiomodulation with Platelet-Rich Fibrin on the Amount of New Bone Formation, Vertical Height and Width of the Buccolingual Alveolar Ridge, Pain Reduction, Width of Keratinized Gingiva, Bone Density

Design
Randomized, Single-Blinded Clinical Trial with Two Parallel Groups design of 36 patients. Rand Function of Excel Software used for Randomization.

Settings and conduct
In the PRF Group, 10 ml of Blood Samples are taken from Patients in the Experimental Group and Centrifuged at 3000 rpm for 10 Minutes. After Atraumatic Extraction, The Obtained PRF is Placed in the Socket and the Socket is Sutured. In the Photobiomodulation Group, On the Day after the Extraction, a Diode Laser with a Wavelength of 660 nm is used and a Diode Laser with a Wavelength of 970 nm is used for Every Other Day to at least Two Weeks. Clinical and Radiographic Parameters are evaluated by the Measuring Person in Two Different Time Periods, One at the Beginning of the Work after Tooth Extraction and the Other, 8 Weeks later. All the Procedure Are Performed in Touba Dental Clinic.

Participants/Inclusion and exclusion criteria
Inclusion Criteria: Patients Over 18 Years of Age with Indications for Extraction of Anterior Teeth and Premolars of the Maxilla and Mandible without the Need for Surgery; ASA I-II Patients Exclusion Criteria: Poor Oral Hygiene; Pregnant or Lactating Women; Smokers and Alcoholism; Chronic Treatment with Any Drug that Affects Bone Function

Intervention groups
In PRF Group, After Tooth Extraction, the PRF is Placed in the Socket. In the Photobiomodulation Group, On the Day after the Tooth Extraction, a Diode Laser Is Used to Socket Preservation.

Main outcome variables
Vertical Height and Width of the Buccolingual Alveolar Ridge; Soft Tissue Healing; Width of Keratinized Gingiva; pain; Bone Density; Bone Formation

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20230222057497N1**
Registration date: **2023-05-09, 1402/02/19**
Registration timing: **prospective**

Last update: **2023-05-09, 1402/02/19**
Update count: **0**

Registration date
2023-05-09, 1402/02/19

Registrant information
Name
Avideh Maboudi
Name of organization / entity
Country
Iran (Islamic Republic of)
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Email address
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2023-05-31, 1402/03/10
Expected recruitment end date
2023-09-01, 1402/06/10
Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical and Radiographic Evaluation of the Effect of Using Photobiomodulation in Comparison with Platelet-Rich Fibrin on Dental Sockets Healing: A Single-blind Randomized Clinical Trial

Public title

Comparison of the Effect of Using Photobiomodulation with Platelet-Rich Fibrin on Dental Sockets Healing

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients over 18 Years of Age Referring to the Special Clinic of the Sari Dental Faculty who have Extensive Irreparable Caries, Failed Root Canal Therapy, Periodontal Disease, Tooth Fracture, Indications for Extraction of Anterior Teeth and Premolars (Maxilla and Mandible) Intact Surrounding Alveolar Bone (Remaining Bone at least Two-Thirds of the Root Length) Tooth Socket with Four Healthy Walls after Extraction Patients Who Willing to Participate in the Study Teeth that Do not Require Surgical Methods to Remove and Do not Require Using of Surgical Burs Patients Who have the Ability to Participate in Examinations and Follow-up ASA I-II Patinets

Exclusion criteria:

Patients with Poor Oral Hygiene Pregnant or Lactating Women or Patients Who are Planning to Get Pregnant Smokers (More than ten Cigarettes per Day) and Alcoholism Patients with Uncontrolled Systemic Disease and History of Head and Neck Radiotherapy and Weak Immune System Chronic Treatment with Any Drug that Affects Bone Function: Heparin, Cyclosporine, Bisphosphonate, Chemotherapy Drugs Presence of Periapical or Periodontal Considerable Lesions around the Corresponding Teeth and Presence of Dehiscence and Fenestration in the Buccal Bone Plate Contraindications for Tooth Extraction Allergy to Any of the Study Products A Severe Acute Infection or Any Other Factor that Limits the Opening of the Mouth

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: **36**

Randomization (investigator's opinion)

Randomized

Randomization description

Using block classification, the samples will be assigned to two groups: C (control group (atraumatic extraction only) and T (intervention group (platelet-rich fibrin (PRF) along with photobiomodulation))). The blocking process is done using Excel software and the samples will be placed in 9 blocks of 4 (the total sample size is 36). We will have six types of blocks of 4 such as TTCC, TCTC, TCCT, CCTT, CTCT, CTTC, where T is for the intervention group and C is for the control group. Using Excel software, numbers will be randomly generated 9 times with the RANDBETWEEN command in the range of 1 to 6 and according to the production values of one of the blocks (for a production number 1 CTTC block, for a production number 2 CTCT blocks and so on) Samples will be allocated. For example, four people have come to the center, two people are supposed to enter the intervention group and two people are in the control group. In the Excel software, between the number one and six, the number two is supposed to be chosen by chance, so these four people are assigned to the CTCT block in the order of reference. In fact, the first person enters the control group, the second person enters the intervention group, the third person enters the control group, and the fourth person enters the intervention group.

Blinding (investigator's opinion)

Single blinded

Blinding description

The Study Sequence will be hidden from the Person who Measures (Radiologist, Periodontist).

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

Third floor, Mazandaran University of Medical Sciences, Research and Technology Deputy Buildin, Moalem Square

City

Sari

Province

Mazandaran

Postal code

4814969616

Approval date

2023-01-07, 1401/10/17

Ethics committee reference number

IR.MAZUMS..REC.1401.427

Health conditions studied

1

Description of health condition studied
Platelet-Rich Fibrin, Photobiomodulation
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
"Vertical height" and "buccolingual" width of alveolar ridge, "Soft tissue healing", "Keratinized gingival width", "Pain", "Bone density"
Timepoint
At the beginning of the study (before the start of the study) and 8 weeks after tooth extraction
Method of measurement
Periodontal Probe, Visual Analogue Scale, Cone Beam CT Scan, Inspection, Fractal Analysis

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: The nurse takes 10 ml of a blood sample from the median cubital vein of each patient and puts it in a dry test tube without anticoagulant. Then, they will be centrifuged in a centrifuge machine (BioHorizon,USA) at a speed of 3000 rpm for 10 minutes. The obtained PRF will be separated using a sterile tweezer. The PRF will be placed inside the socket and sutured with a 4-0 polyglycolic acid suture with a 19 needle (Suchers-Iran) using figure 8 suturing technique
Category
Treatment - Other

2

Description
Control group: Immediately after tooth extraction, the socket is sutured with a 4-0 polyglycolic acid suture with a 19 needle (Suchers-Iran) using figure 8 suturing technique. The day after the extraction, the periodontist Uses a diode laser (Dentsply Sirona, Germany) with a wavelength of 660 nm, power of 100 MW, and energy density of 2 j/cm2 for 10 seconds in three positions, i.e., buccally, lingually, and diagonally to the edge of the tissue. She will also perform it from the socket with the minimum possible distance to repair the soft tissue. Then, she will continuously use diode laser radiation (Dentsply Sirona, Germany) with a wavelength of 970 nm, power of 200 MW, and an energy density of 6 j/cm2 for 20 seconds to repair the hard tissue. The laser is irradiated by a low-power head (8 mm multi tip with a cross-sectional area of 1.5 cm2) in the buccal and lingual areas so that it covers half the length of the root each time. This protocol is repeated on the day after the extraction and then every other day for at least two weeks (1, 3, 6, 8, 10, 13, 15)
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Tuba clinic
Full name of responsible person
Avideh Maboudi
Street address
Tuba clinic, Dr. Beheshti Blvd., Khazar Square
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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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Street address
Tuba clinic, Dr. Beheshti Blvd., Khazar Square
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Phone
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Email
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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

Avideh Maboudi

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

Street address

Sadaf Complex, Narenj Alley, 15 Khordad Ave

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Avideh Maboudi

Position

Associate professor

Latest degree

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Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

Avideh Maboudi

Position

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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

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

Title and more details about the data/document

Vertical Height and Width of the Buccolingual Alveolar Ridge; Soft Tissue Healing; Width of Keratinized Gingiva; pain; Bone Density

When the data will become available and for how long

The access period starts 6 months after the results are published

To whom data/document is available

Researchers working in academic and scientific institutions

Under which criteria data/document could be used

The request should be sent to the responsible person after consultation with the research team, the data will be provided to the requesting person and it is necessary to give reference to the data owners in the articles or wherever the data is going to be used.

From where data/document is obtainable

Avideh Maboudi Sadaf Complex, Narenj Alley, 15

Khordad Ave, Postal code 4818865454 989111531637 981133263345 avideh48188@yahoo.com

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

Send the reason for the request to avideh48188@yahoo.com email address

Comments