Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

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

Protocol summary

Study aim

Study 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, A 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 Control Group, the Teeth are extracted with Minimal Trauma and The Sockets Were Sutured. 10 ml of Blood Samples are taken from Patients in the Experimental Group and Centrifuged at 3000 rpm for 10 Minutes. After Extraction, The Obtained PRF is Placed in the Socket and The Socket is Sutured. 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 the Control Group, only Tooth Extraction will be done. In the Experimental Group, Diode Laser Combined with Platelet-Rich Fibrin is used to Socket Preservation after tooth extraction

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: **IRCT20230305057619N1**
Registration date: **2023-05-13, 1402/02/23**
Registration timing: **prospective**

Last update: **2023-05-13, 1402/02/23**
Update count: **0**

Registration date

2023-05-13, 1402/02/23

Registrant information

Name
Avideh Maboudi
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 11 3326 3345
Email address
kouchakiz@yahoo.com

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 with Platelet-Rich Fibrin on Dental Sockets Healing in Comparison of the Control Group: A Single-Blind Randomized Clinical Trial

Public title

Effect of 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 Hygine 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
- Data analyser

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 evaluates the outcome (Radiologist, Periodontist).

Placebo

Not used

Assignment

Other

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

4816895475

Approval date
2023-02-12, 1401/11/23
Ethics committee reference number
IR.MAZUMS.REC.1401.497

Health conditions studied

1

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

2

Description of health condition studied
Photobiomodulation
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Vertical height of alveolar ridge
Timepoint
At the beginning of the study (before the start of the intervention) and 8 weeks after tooth extraction
Method of measurement
Cone Beam CT Scan

2

Description
buccolingual width of alveolar ridge
Timepoint
At the beginning of the study (before the start of the intervention) and 8 weeks after tooth extraction
Method of measurement
Cone Beam CT Scan

3

Description
Soft tissue healing
Timepoint
2, 7 and 14 days after tooth extraction
Method of measurement
Modified soft tissue healing index

4

Description
Keratinized gingival width
Timepoint
At the beginning of the study (before the start of the intervention) and 8 weeks after tooth extraction
Method of measurement
Periodontal probe

5

Description
Pain
Timepoint
24, 48 and 72 hours after tooth extraction
Method of measurement
Visual Analogue Scale

6

Description
Bone density
Timepoint
At the beginning of the study (before the start of the intervention) and 8 weeks after tooth extraction
Method of measurement
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 beplaced inside the socket and 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

2

Description
Control group: After extraction the tooth and suture the socket with 0-4 polyglycolic acid suture with a 19 needle (Suchers-Iran), sterile gauze impregnated with normal

saline is placed on the socket and no other action is taken

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

City

Sari

Province

Mazandaran

Postal code

4816895475

Phone

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Email

avideh48188@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Avideh maboudi

Street address

Tuba clinic, Dr. Beheshti Blvd., Khazar Square

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sari

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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

Specialist

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Person responsible for updating data

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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

All data is potentially shareable after de-identifying individuals.

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

The data can be obtained through the email of the responsible researcher. avideh48188@yahoo.com

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

Details of the new research design and the process to be performed on the documentation should be emailed to the responsible investigator to allow access to the data.

Comments