

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Comparing the Effect of Platelet Rich Fibrin Injection with Microneedling Versus Normal Saline Injection with Microneedling in the Treatment of Atrophic Burn Scars: A Randomized Clinical Trial

Protocol summary

Study aim

Comparison of the Effect of Platelet-Rich Fibrin Injection and Microneedling versus Microneedling Alone in the Treatment of Atrophic Scars Resulting from Burns.

Design

Phase 3, two-arm, parallel group, double-blind, randomized trial involving 21 patients. Randomization is achieved using balanced block randomization.

Settings and conduct

Place of study: Rasool Akram Hospital; Study population: 26 patients with bilateral atrophic burn scars; Type of blinding: patient and evaluator; Method of blinding: request patients to close their eyes during injections and not informing the evaluator of the scars` grouping.

Participants/Inclusion and exclusion criteria

Inclusion criteria: people aged 18-60; The presence of bilateral burns. Exclusion criteria: patients with underlying disease disrupting collagen synthesis, blood coagulation disorders and immunocompromised patients; Pregnant patients or those who intend to become pregnant; Patients with any type of malignancy; heavy smokers; Patients who have undergone scar treatment in the 3 months leading up to the start of the study; Patients who are mentally incapable of giving consent to participate in the study.

Intervention groups

Intervention Group: Injection of Platelet-Rich Fibrin along with Microneedling. Control Group: Injection of Normal Saline along with Microneedling.

Main outcome variables

Changes in the Patient and Observer Scar Assessment Scale (POSAS)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20231209060308N1**

Registration date: **2024-01-12, 1402/10/22**

Registration timing: **prospective**

Last update: **2024-01-12, 1402/10/22**

Update count: **0**

Registration date

2024-01-12, 1402/10/22

Registrant information

Name

Farzan Moodi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8601 7501

Email address

dr.farzanmoodi@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-02-20, 1402/12/01

Expected recruitment end date

2024-03-20, 1403/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the Effect of Platelet Rich Fibrin Injection with Microneedling Versus Normal Saline Injection with

Public title

Effect of Platelet Injection on Burn Scar

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Presence of at least two atrophic burn scars anywhere on the body in a symmetrical pattern. Age between 18-60 years. Both male and female genders are included in this study.

Exclusion criteria:

Patients with underlying conditions such as diabetes, blood clotting disorders, and immunodeficiency disorders. Pregnant patients or those planning to become pregnant. Patients diagnosed with any malignancy. Smokers with more than one pack of cigarettes per day (Heavy Smokers) Patients who have received another treatment for their scars within the 3-month period prior to the commencement of the intervention, which may have led to collagen stimulation. Patients who do not have the mental capacity to provide consent for participation in the study or to respond to researchers' inquiries.

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data and Safety Monitoring Board

Sample size

Target sample size: **21**

More than 1 sample in each individual

Number of samples in each individual: **2**

Including both sides of the face, both sides of the chin, and the upper neck in cases not connected to facial burns, as well as the back of the hands up to the wrists. It should be noted that not all individuals have all these types of burns.

Randomization (investigator's opinion)

Randomized

Randomization description

For randomization in this study, the block balanced randomization method will be utilized. Accordingly, we prepare packets for the number of patients, and within each packet, we allocate the treatment and control arms alternately to the right and left side of the face. For instance, in the first packet, the treatment arm for the right hand scar and the control arm for the left hand scar, and in the next packet, this arrangement will be reversed. To ensure that only the evaluator is aware of the arms, abbreviated symbols such as A and B will be used on each paper. Then, when the patient visits, they will be asked to choose one of the packets, and based on

their selection, the treatment and control arms will be determined. Thus, at the end of the study, each body part in half of the patients will be in the treatment arm, and in the other half, it will be in the control arm.

Blinding (investigator's opinion)

Double blinded

Blinding description

Clinical Caregiver and Evaluator Blinding: In this study, the role of the clinical caregiver and evaluator is assigned to one person, who also serves as the primary physician of the patient. For blinding, no information related to the treatment and control arms is provided during any of the initial assessment stages and follow-up sessions, which occur one month and three months after the treatment. The physician is required to evaluate the patient's scar without knowledge of these two arms. Participant Blinding: To blind the participants regarding the treatment and control arms, normal saline solution is injected instead of PRF in the control arm. Due to the color difference between these two substances (PRF and normal saline), patients are requested to close their eyes for greater comfort during the injection process. With this method, the patient will not be aware of the color difference between the two injected substances.

Placebo

Used

Assignment

Parallel

Other design features

Due to the necessity of ensuring that patients are not deprived of effective scar treatment, all scars will undergo standard treatment involving collagen stimulation with microneedling. Microneedling will be performed using Dermapen, which has disposable needles at the end. The length of these needles will be set at 1.5-2 millimeters, and the device speed will be set to high speed. The device will be moved perpendicular to the scar, covering the entire scar, to induce pinpoint bleeding. For the preparation of Injectable PRF, the standard centrifugation method introduced by Miron et al. will be employed. Blood will be centrifuged for 3 minutes at a gravitational acceleration of 60. Depending on the physician's judgment and the extent of the scar, the desired volume of PRF will be obtained by drawing blood from the patient at a rate of two and a half times the desired PRF volume. Subsequently, the patient's collected blood will be evenly divided into two test tubes and placed in the centrifuge device in a symmetrical arrangement. Following the device settings protocol with gravitational acceleration (g) set at 60, and the number of revolutions per minute (rpm) variable depending on the device, centrifugation will be performed for 3 minutes. The resulting composition will include blood cells at the bottom of the tube and PRF at the top. The separated PRF will then be injected intradermally into the scar on the treatment arm before coagulation. Additionally, normal saline solution will be used for injection into the control arm to blind the patient. Since there is no study proving the effect of normal saline in the collagen synthesis process and similar use in other studies, it is considered a suitable substance for patient blinding.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committees of Directorate of Health,
Rescue and Treatment of Police Headquarter of I

Street address

Health, Relief, and Treatment Deputy of NAJA, Edward
Brown Street, North Karegar Street, Enqelab Square

City

Tehran

Province

Tehran

Postal code

۱۴۱۷۹۴۴۶۱

Approval date

2023-12-09, 1402/09/18

Ethics committee reference number

IR.SBMU.TEB.POLICE.REC.1402.076

Health conditions studied

1

Description of health condition studied

Burn scar

ICD-10 code

L90.5

ICD-10 code description

Scar conditions and fibrosis of skin

Primary outcomes

1

Description

Patient and Observer Scar Assessment Scale (POSAS)
points

Timepoint

In the first visit, the initial treatment session, one month,
and three months after the last treatment session.

Method of measurement

Patient and Observer Scar Assessment Scale (POSAS)

2

Description

Changes in skin tone evenness

Timepoint

In the initial treatment session, one month, and three
months after the last treatment session.

Method of measurement

VisioFace

3

Description

Local inflammatory or irritating adverse events

Timepoint

Within two weeks after each treatment session

Method of measurement

Patient visit or report

4

Description

Hemosiderin staining

Timepoint

Within two weeks after each treatment session

Method of measurement

Patient visit or report

5

Description

Herpes

Timepoint

Within two weeks after each treatment session

Method of measurement

Patient visit or report

6

Description

Hypersensitivity reactions

Timepoint

Within two weeks after each treatment session

Method of measurement

Patient visit or report

Secondary outcomes

empty

Intervention groups

1

Description

Control group: Receiving microneedling along with
injection of normal saline.

Category

Placebo

2

Description

Intervention group: Receiving microneedling along with
injection of platelet-rich fibrin into the specific scar area
on the treatment arm, derived from the patient's blood
processed in a centrifuge set on 60G.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Hazrat Fatemeh Specialized Educational and Medical Center

Full name of responsible person

Farzan Moodi

Street address

Hazrat Fatemeh Specialized Educational and Medical Center; Next to Shafaq Park; 21st Street; Asadabadi Street; Yousef Abad

City

Tehran

Province

Tehran

Postal code

1433933111

Phone

+98 21 8871 7272

Fax

+98 21 8810 7658

Email

crtfatima@iums.ac.ir

Web page address

<https://crtfatima.iums.ac.ir/>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Dr Kazem Mousavizadeh

Street address

Iran University of Medical Sciences, Next to Milad Tower, Hemmat highway

City

Tehran

Province

Tehran

Postal code

۱۳۴۹۶۱۴۵۳۵

Phone

+98 21 86701

Email

farzan.cod@gmail.com

Web page address

<https://iums.ac.ir/>

Grant name

Grant code / Reference number

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

No

Title of funding source

Center for Applied Research, Deputy of Health, Relief, and Treatment, NAJA

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

Other

Person responsible for general inquiries

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Farzan Moodi

Position

General Physician

Latest degree

Medical doctor

Other areas of specialty/work

Dermatology

Street address

Unit 3, No. 14, 33rd street, Gisha

City

Tehran

Province

Tehran

Postal code

1447934161

Phone

+98 21 8601 7501

Email

dr.farzanmoodi@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Farzan Moodi

Position

General Physician

Latest degree

Medical doctor

Other areas of specialty/work

Dermatology

Street address

Unit 3, No. 14, 33rd street, Gisha

City

Tehran

Province

Tehran

Postal code

1447934161

Phone

+98 915 771 7179

Email

dr.farzanmoodi@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Farzan Moodi

Position

General Physician

Latest degree

Medical doctor

Other areas of specialty/work

Dermatology

Street address

Unit 3, No. 14, 33rd street, Gisha

City

Tehran

Province

Tehran

Postal code

1447934161

Phone

+98 21 8601 7501

Email

dr.farzanmoodi@gmail.com

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

Non-identifiable patient data will be made available after analysis in the article extracted from the accessible study. These include demographic data and changes in variables related to patients' burn scar.

When the data will become available and for how long

Immediately after the publication of the article.

To whom data/document is available

Aggregate data will be accessible for all individuals.

Individual data, upon request, will be provided by the corresponding author.

Under which criteria data/document could be used

All investigations leading to the improvement of the research project's outcomes and the advancement of burn scar treatment are feasible.

From where data/document is obtainable

Email should be sent to the corresponding author in the article.

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

The requester should introduce themselves, specify the type of data requested, provide the reason for the request, and outline the investigations they would like to conduct in their message.

Comments