Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparing the effectiveness of PRP injection with Noncross-linked hyaluronic acid injection and PRP injection in combination with Noncross-linked hyaluronic acid in patients treated with CO2 fractional laser in the treatment of atrophic burn scars; A double-blind randomized clinical trial

Protocol summary

Study aim

General goals: Comparative study of platelet rich plasma and noncross linked hyaluronic acid injections in the treatment of atrophic burn scars in patients treated with fractional CO2 laser

Design

Clinical trial with control group, double-blind, randomized, on 10 patients. The rand function of Excel software was used for randomization.

Settings and conduct

Interventions will be performed in the skin and stem cells center. The patient under study and the two dermatologists evaluating atrophic scar lesions are not aware of the type of injection performed in each area. The scar areas of patients are divided into four parts.In one area, PRP is injected, in another area, non-cross-linked hyaluronic acid, and in the third area, a combination of the two, and in the fourth area, physiological serum is injected. All patients are re-injected after one month.

Participants/Inclusion and exclusion criteria

The inclusion criteria for the study included all 10 patients who were diagnosed with atrophic burn scars and were treated with CO2 fractional laser, but did not fully recover. Exclusion criteria: Age less than 18 years or more than 50 years; Atrophic scar created in the last 6 months; Performing therapeutic intervention for atrophic scar in the previous one month, except CO2 fractional laser; Bleeding and coagulation disorders; Pregnancy; Breastfeeding

Intervention groups

In this study, a certain number of volunteer patients with atrophic burn scars will be selected based on the inclusion and exclusion criteria. The scar areas of patients are divided into four parts. In one area, platelet-rich plasma is injected, in another area, non-cross-linked hyaluronic acid, and in the third area, a combination of the two, and in the fourth area, physiological serum is injected.

Main outcome variables

Improvement of severity of atrophic burn scar

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220808055641N1**
Registration date: **2022-09-11, 1401/06/20**
Registration timing: **registered_while_recruiting**

Last update: **2022-09-11, 1401/06/20**
Update count: **0**

Registration date

2022-09-11, 1401/06/20

Registrant information

Name

Alireza Jafarzadeh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 919 890 7445

Email address

alirezajafarzadeh8@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-09-06, 1401/06/15

Expected recruitment end date
2023-09-06, 1402/06/15
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparing the effectiveness of PRP injection with Noncross-linked hyaluronic acid injection and PRP injection in combination with Noncross-linked hyaluronic acid in patients treated with CO2 fractional laser in the treatment of atrophic burn scars; A double-blind randomized clinical trial

Public title
Investigating the effectiveness of PRP and Noncross linked hyaluronic acid in the treatment of atrophic burn scars.
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Existence of atrophic burn scar treated with CO2 fractional laser
Exclusion criteria:
Age less than 18 years or more than 50 years Atrophic scar created in the last 6 months Conducting therapeutic intervention for atrophic scar in the last one month except CO2 fractional laser Bleeding and coagulation disorder pregnancy breastfeeding
Age
From **18 years** old to **50 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size
Target sample size: **10**
More than 1 sample in each individual
Number of samples in each individual: **4**
In one area of the selected areas, platelet-rich plasma is injected, in another area, noncross-linked hyaluronic acid is injected, in the third area, a combination of platelet-rich plasma and noncross-linked hyaluronic acid is injected, and in the fourth area, physiological serum is injected as a control group.
Randomization (investigator's opinion)
Randomized
Randomization description
The burn scar of all patients is divided into four parts and in a simple randomization and individually based on the random table of numbers, each of the parts is subjected to a therapeutic intervention from among the four mentioned interventions, and the recovery rate is as before and After, each area will be evaluated and then the improvement in the four mentioned areas will be compared.
Blinding (investigator's opinion)
Double blinded
Blinding description
The participants in the study, as well as the physician evaluating the clinical outcome, as well as the statistician analyzing the data, are kept blind to the type of injection performed at each location.
Placebo
Used
Assignment
Single
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Tehran University of Medical Sciences
Street address
No 6, Avesta Ave, Azadi Blvd, Tehran
City
Tehran
Province
Tehran
Postal code
1345643546
Approval date
2022-08-13, 1401/05/22
Ethics committee reference number
IR.TUMS.MEDICINE.REC.1401.377

Health conditions studied

1

Description of health condition studied
burn atrophic scar
ICD-10 code
L90
ICD-10 code description
Atrophic disorders of skin

Primary outcomes

1

Description
improvement of burn atrophic scar
Timepoint
The beginning of the study and 1 month after the start of the study and 3 months after the start of the study
Method of measurement

vancouver scar scale;sonography;visioface;biometery;cutometery,physician global assessment score;patient global assessment score

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1:Injection of platelet-rich plasma in a volume of 2 cc, which is obtained after collecting whole blood from the study subjects, in the amount of 10 cc and centrifuging it at 5600 rpm, and contains plasma rich in platelet blood cells. And one time at the beginning of the study and the other time, one month after the first time, it is injected as an intradermal injection in the place of the burn scar.

Category

Treatment - Drugs

2

Description

Intervention group 2: njection of platelet-rich plasma in a volume of 2 cc, which is obtained after collecting whole blood from the study subjects, in the amount of 10 cc and centrifuging it at 5600 rpm, and contains plasma rich in platelet blood cells, along with the injection of 2 cc of non-cross-linked hyaluronic acid in the form of 1 cc ready-to-injectable syringes of Juviderm, which are injected intradermally for each person, at the site of the burn scar. Each person is re-injected twice, one time at the beginning of the study and the second time, one month after the first time.

Category

Treatment - Drugs

3

Description

Intervention group3 : Injection of non-cross-linked hyaluronic acid with a volume of 2 cc in the form of 1 cc ready-to-injectable syringes of Juviderm company, which two 1 cc syringes for each person are injected intradermally at the site of the burn scar. Each person is re-injected twice, one time at the beginning of the study and the second time, one month after the first time.

Category

Treatment - Drugs

4

Description

Control group: injection of 2 cc of injectable normal saline, including sodium chloride solution with a concentration of 0.9% of Ghazi Pharmaceutical Company, once at the beginning of the study and another time, one month after the first time, as an intradermal injection, at the site The burn scar is injected.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Hazrat-E-Fatemeh Plastic and Reconstructive Surgery Hospital

Full name of responsible person

Alireza Jafarzadeh

Street address

No. 6, Avesta Ave, Azadi Blvd, Tehran Town

City

Tehran

Province

Tehran

Postal code

1346544457

Phone

+98 919 890 7445

Email

alirezajafarzadeh8@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

mohammad ali Nilforoushzadeh

Street address

No 4 Maryam, Dead End South Andarzgo Blvd, Kamraniyeh, Tehran

City

Tehran

Province

Tehran

Postal code

1234356765

Phone

+98 21 2665 7541

Email

nilforoushzadeh@gmail.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Tehran 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
Iran University of Medical Sciences
Full name of responsible person
Alireza Jafarzadeh
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
Dermatology
Street address
No.6, ahmadzadeh ardabili Ave, Avesta Blvd, Azadi Blvd, Tehran Town
City
Tehran
Province
Tehran
Postal code
6567634523
Phone
+98 919 890 7445
Fax
Email
Alirezajafarzadeh8@gmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Alireza Jafarzadeh
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
Dermatology
Street address
No.6, ahmadzadeh ardabili Ave, Avesta Blvd, Azadi Blvd, Tehran Town
City
Tehran
Province
Tehran
Postal code
13244357653
Phone
+98 919 890 7445
Fax
Email
Alirezajafarzadeh8@gmail.com

Person responsible for updating data

Contact
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Alireza Jafarzadeh
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
Dermatology
Street address
No.6, ahmadzadeh ardabili Ave, Avesta Blvd, Azadi Blvd, Tehran Town
City
Tehran
Province
Tehran
Postal code
13244543654
Phone
+98 919 890 7445
Fax
Email
Alirezajafarzadeh8@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
Yes - There is a plan to make this available
Title and more details about the data/document
After the completion of the study, all patient data will be shared through the article after de-identification.
When the data will become available and for how long
Access to data starts immediately after the publication of the article.
To whom data/document is available
There are no restrictions on people's access to data.
Under which criteria data/document could be used
There is no restriction on the type of data usage.
From where data/document is obtainable
rasool-E-akram hospital, niyayesh Ave, satar khan Blvd, Tehran 00989198907445 alireza jafarzadeh alirezajafarzadeh8@gmail.com
What processes are involved for a request to access data/document
After receiving the email from the applicant, the data will

be sent within a maximum of 6 months.

Comments