

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of the effectiveness of platelet-rich plasma injection with noncross-linked hyaluronic acid injection and platelet-rich plasma injection in combination with noncross linked hyaluronic acid in patients treated with fractional CO2 laser in the treatment of atrophic acne scars ; A double-blind clinical trial

Protocol summary

Study aim

Comparative study of platelet rich plasma and noncross linked hyaluronic acid injections in the treatment of atrophic acne 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 the atrophic scar lesions are not aware of the type of injection performed in each area. Patients are divided into two groups a and b. In both groups, in one half of the face, a combination of prp and non-cross-linked hyaluronic acid is injected. In group a, on the opposite side, prp is injected. and in group b, non-cross-linked hyaluronic acid is injected.

Participants/Inclusion and exclusion criteria

The inclusion criteria for the study included all 10 patients who were diagnosed with atrophic acne scars and were 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; Performing therapeutic intervention for atrophic scar in the previous one month, except CO2 fractional laser; Bleeding and coagulation disorders; Pregnancy; Breastfeeding

Intervention groups

Patients are divided into two groups a and b. In group a, in the atrophic acne scars of one half of the face, platelet-rich plasma injection is performed, and in the opposite half, the combination of platelet-rich plasma and non-cross-linked hyaluronic acid is performed. In

group b, in one half of the face, non-cross-linked hyaluronic acid injection is performed. Cross-link and in the opposite half, the simultaneous injection of plasma rich in platelets and hyaluronic acid is performed.

Main outcome variables

Improvement of severity of atrophic acne scar

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220808055641N2**

Registration date: **2022-09-26, 1401/07/04**

Registration timing: **registered_while_recruiting**

Last update: **2022-09-26, 1401/07/04**

Update count: **0**

Registration date

2022-09-26, 1401/07/04

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

2022-09-21, 1401/06/30

Expected recruitment end date

2023-05-20, 1402/02/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effectiveness of platelet-rich plasma injection with noncross-linked hyaluronic acid injection and platelet-rich plasma injection in combination with noncross linked hyaluronic acid in patients treated with fractional CO2 laser in the treatment of atrophic acne scars ; A double-blind clinical trial

Public title

Comparing the efficacy of platelet-rich plasma and non-cross-linked hyaluronic acid injection and their combination in the treatment of atrophic acne scars

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Existence of atrophic acne 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: **2**

All patients are divided into two groups a and b by simple randomization and individually based on the random table of numbers. In group a, in atrophic acne scars, one half of the face is injected with platelet-rich plasma, and in the opposite half, simultaneous injection of platelet-rich plasma and non-cross-linked hyaluronic acid is performed. In group b, in atrophic acne scars, one half of the face is injected with non-cross-linked hyaluronic acid and the opposite half is injected with platelet-rich plasma and non-cross-linked hyaluronic acid.

Randomization (investigator's opinion)

Randomized

Randomization description

The studied subjects are divided into two groups of 5 a and b by simple randomization and individually, based on the random table of numbers. In group a, one half of the face is injected with platelet-rich plasma and in the opposite half of the face, platelet-rich plasma is injected with non-cross-linked hyaluronic acid. In group b, in one half of the face, non-cross-linked hyaluronic acid injection is performed, and in the opposite half, the combination of platelet-rich plasma and non-cross-linked hyaluronic acid is injected.

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

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Province

Tehran

Postal code

1345643546

Approval date

2022-08-13, 1401/05/22

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1401.376

Health conditions studied**1****Description of health condition studied**

acne atrophic scar

ICD-10 code

L90

ICD-10 code description

Atrophic disorders of skin

Primary outcomes

1

Description

improvement of acne 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

sonography;visioface;biometry;cutometry,physician global assessment score;patient global assessment score

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: 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 another time, one month after the first time, is injected as an intradermal injection, in the place of acne scars of one half of the face in group a.

Category

Treatment - Drugs

2

Description

Intervention group: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. , along with the injection of 2 cc of non-cross-linked hyaluronic acid in the form of 1 cc ready-to-injectable syringes of Juvederm company, which are two 1 cc syringes for each person intradermally, at the acne scar site of one half of the face Group a is injected. 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 group: Injection of non-cross-linked hyaluronic acid with a volume of 2 cc in the form of ready-to-injectable syringes of Juvederm company with a volume of 1 cc, two 1 cc syringes for each person intradermally, at the acne scar site of one half of the face in group b is injected. 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

Intervention group: 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. , along with the injection of 2 cc of non-cross-linked hyaluronic acid in the form of 1 cc ready-to-injectable syringes of Juvederm company, which are two 1 cc syringes for each person intradermally, at the acne scar site of one half of the face Group b is injected. 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

Recruitment centers

1

Recruitment center

Name of recruitment center

Hazrat-E-Fatemeh Plastic and Reconstructive Surgery Hospital

Full name of responsible person

Alireza Jafarzadeh

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Mohammadali Nilforoushzadeh

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

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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

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Person responsible for scientific inquiries

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Name of organization / entity

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Full name of responsible person

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Position

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Person responsible for updating data

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Full name of responsible person

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Position

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Latest degree

Medical doctor

Other areas of specialty/work

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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 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