Clinical Trial Protocol
Iranian Registry of Clinical Trials

31 May 2026

A comparative study of the efficacy of Wharton jelly mesenchymal stem cell conditioned medium injection combined with hyaluronic acid and platelet rich plasma injection combined with hyaluronic acid in the treatment of atrophic acne scars in patients treated with CO2 fractional laser: a double-blind clinical trial

Protocol summary

Study aim

A comparative study of the efficacy of Wharton jelly mesenchymal stem cell conditioned medium injection combined with hyaluronic acid and platelet rich plasma injection combined with hyaluronic acid in the treatment of atrophic acne scars in patients treated with CO2 fractional laser

Design

Clinical trial with control group, double-blind, randomized, on 20 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, hyaluronic acid injection was performed in one half of the face. In group b, on the opposite side, stem cells conditioned medium was injected, and in group a, prp was also injected.

Participants/Inclusion and exclusion criteria

The inclusion criteria for the study included all 20 patients who were diagnosed with atrophic acne scars and were treated with fractional CO2 laser before the start of the study, but did not fully recovered. Exclusion criteria: Age less than 18 years or more than 60 years; Atrophic scar created in the last 6 months; Performing therapeutic intervention for atrophic scar in the last one month except CO2 fractional laser; Bleeding and coagulation disorders; Pregnancy; Breastfeeding

Intervention groups

All patients are divided into two groups a and b. In group a, one half of the face, prp in combination with hyaluronic acid was injected. in the opposite half hyaluronic acid was injected. In group b, in one half of the face, hyaluronic acid injection is performed and in the opposite half, the injection of stem cell conditioned medium 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: **IRCT20220808055641N3**
Registration date: **2023-01-07, 1401/10/17**
Registration timing: **prospective**

Last update: **2023-01-07, 1401/10/17**
Update count: **0**

Registration date

2023-01-07, 1401/10/17

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
2023-01-20, 1401/10/30
Expected recruitment end date
2023-07-21, 1402/04/30
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
A comparative study of the efficacy of Wharton jelly mesenchymal stem cell conditioned medium injection combined with hyaluronic acid and platelet rich plasma injection combined with hyaluronic acid in the treatment of atrophic acne scars in patients treated with CO2 fractional laser: a double-blind clinical trial

Public title
Comparing the effectiveness of stem cell conditioned medium and platelet-rich plasma injection in combination with noncross-linked hyaluronic acid 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 65 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 **65 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size
Target sample size: **20**
More than 1 sample in each individual
Number of samples in each individual: **2**
In group a, all patients are treated with mesenchymal stem cell conditioned medium in one half of the face in combination with noncross linked hyaluronic acid, and in the opposite half, noncross linked hyaluronic acid is injected alone. In group b, all patients are injected with prp in one half of the face. with noncross-linked hyaluronic acid, and in the opposite half, injection of noncross-linked hyaluronic acid is performed alone.
Randomization (investigator's opinion)
Randomized
Randomization description
The studied subjects are divided into two groups of ten people named a and b by simple randomization. The method of randomization is as follows: when people enter the study, out of twenty envelopes whose contents are completely invisible and ten of them contain the letter a and ten contain the letter b, they choose one envelope. and are placed in group a or b. Also, all people in group a choose one envelope from the other 2 envelopes that contain the letters R and L, and each patient chooses the envelope containing the letter L to inject mesenchymal stem cell conditioned medium in The combination with non-cross-linked hyaluronic acid will be performed on the acne scar on the left side of the face, and each patient will be injected on the right side by selecting the envelope containing the letter R. Also, all the people of group b chose one envelope from the two envelopes containing the letters R and L. If the letter L is inserted, prp injection in combination with non-cross-linked hyaluronic acid on the left side of the face, and if the letter R is inserted, the above injection. It will be done on the right side of the face. Obviously, in both groups a and b, non-cross-linked hyaluronic acid will be injected alone on the opposite side. In group A, all patients were injected with mesenchymal stem cell conditioned medium in one half of the face in combination with noncross linked hyaluronic acid, and in the opposite half, noncross linked hyaluronic acid was injected alone. In group B, all patients were injected with PRP in combination with noncross linked hyaluronic acid in one half of the face, and noncross linked hyaluronic acid was injected alone in the opposite half.
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
Not used
Assignment
Single
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
کمیته اخلاق دانشگاه علوم پزشکی تهران
Street address
No 6, Avesta Ave, Azadi Blvd, Tehran
City
Tehran
Province
Tehran

Postal code
1345643546
Approval date
2022-12-22, 1401/10/01
Ethics committee reference number
IR.TUMS.MEDICINE.REC.1401.616

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;biometery;cutometery,physician global assessment score;patient global assessment score

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: In group A, all patients in one half of the face received 2 cc mesenchymal stem cell conditioned medium from Wharton jelly in combination with 2 cc injection of noncross linked hyaluronic acid, which is available in 5 cc vials under the name of cocktail 532 of Revitacare company. and two 1 cc syringes are injected for each patient. In all patients, a re-injection is performed after 2 months.
Category
Treatment - Drugs

2

Description
Intervention group: In group a, all patients in the opposite half of the face are injected with noncross linked hyaluronic acid, which is available in the form of 5 cc vials under the name of cocktail 532 of Revitacare company, and two 1 cc syringes are injected for each patient. In all patients, a re-injection is performed after 2 months.
Category
Treatment - Drugs

3

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. , together with the injection of 2 cc of non-cross-linked hyaluronic acid in the form of 2 1 cc syringes prepared from 5 cc vials of Revitacare Company's cocktail 532, it is injected at the site of acne scars on one half of the face in group a. 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: In group b, all patients in the opposite half of the face are injected with noncross linked hyaluronic acid, which is available in the form of 5 cc vials under the name of cocktail 532 of Revitacare company, and two 1 cc syringes are injected for each patient. In all patients, a re-injection is performed after 2 months.
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
Mohammadali 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
رزیدنت
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
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
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
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 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