Clinical Trial Protocol
Iranian Registry of Clinical Trials

12 Sep 2026

Evaluation and comparison of the Efficacy of Stromal Vascular Fraction (SVF) Combined with Non-Cross-Linked Hyaluronic Acid Versus Platelet-Rich Plasma (PRP) combined with Non-Cross-Linked Hyaluronic Acid in the treatment of patients with atrophic acne scars undergoing fractional CO_2 Laser therapy

Protocol summary

Study aim

To compare the efficacy of Stromal Vascular Fraction and Platelet Rich Plasma, both combined with non cross linked hyaluronic acid, in improving atrophic acne scars after fractional carbon dioxide laser therapy

Design

A randomized, single blinded, phase 2 clinical trial with a comparison group and split face design on 30 patients. Allocation will be performed using permuted blocks of four

Settings and conduct

This randomized clinical trial with a split face design will be conducted on patients with atrophic acne scars at Hazrat Fatemeh Educational and Therapeutic Center for Reconstructive and Plastic Surgery. After obtaining informed consent, patients will receive fractional carbon dioxide laser therapy followed by injection of Stromal Vascular Fraction combined with non cross linked hyaluronic acid on one side of the face and Platelet Rich Plasma combined with non cross linked hyaluronic acid on the opposite side. Allocation of interventions will be randomized. The outcome assessor will be blinded to the intervention type on each side of the face.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with atrophic acne scars, candidates for fractional carbon dioxide laser therapy, with informed consent. Exclusion criteria: Diseases affecting wound healing, active skin diseases, medications affecting immunity or skin healing, pregnancy or breastfeeding, allergy to study materials

Intervention groups

Intervention group: Injection of Stromal Vascular Fraction combined with non cross linked hyaluronic acid on one side of the face. Comparison group: Injection of Platelet Rich Plasma combined with non cross linked hyaluronic acid on the opposite side of the face

Main outcome variables

Improvement of atrophic acne scars based on clinical evaluation; patient satisfaction with treatment outcome

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20260802070498N1**
Registration date: **2026-08-26, 1405/06/04**
Registration timing: **prospective**

Last update: **2026-08-26, 1405/06/04**
Update count: **0**

Registration date

2026-08-26, 1405/06/04

Registrant information

Name

Fahime Sarjamei

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8871 7272

Email address

drfahimesarjamei@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2026-09-11, 1405/06/20

Expected recruitment end date

2026-09-11, 1405/06/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation and comparison of the Efficacy of Stromal Vascular Fraction (SVF) Combined with Non-Cross-Linked Hyaluronic Acid Versus Platelet-Rich Plasma (PRP) combined with Non-Cross-Linked Hyaluronic Acid in the treatment of patients with atrophic acne scars undergoing fractional CO_2 Laser therapy

Public title

The Efficacy of Stromal Vascular Fraction (SVF) combined with Non-Cross-Linked Hyaluronic Acid on Atrophic Acne scars undergoing Fractional CO_2 Laser therapy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age 18 to 45 years Presence of atrophic facial acne scars Mild to severe atrophic acne scars requiring fractional CO_2 laser therapy Willingness and ability to participate in the study and complete the follow-up period Provision of written informed consent No history of invasive acne scar treatments within the previous 6 months Eligibility to undergo fractional CO_2 laser therapy and the study interventions

Exclusion criteria:

Active systemic or autoimmune diseases History of keloid or hypertrophic scars Use of anticoagulant drugs or systemic retinoids within the past six months Pregnancy or breastfeeding Active infection at the treatment site History of hypersensitivity to any of the materials used in SVF, PRP, and luxiva

Age

From **18 years** old to **45 years** old

Gender

Both

Phase

2

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **12**

More than 1 sample in each individual

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

Both sides of the face in each patient will be included in the study.

Randomization (investigator's opinion)

Randomized

Randomization description

After confirming the eligibility criteria and obtaining written informed consent, each patient will be randomly assigned to receive a combination of Stromal Vascular Fraction (SVF) and nanocross-linked Hyaluronic Acid (Luxiva) on one half of the face, while the contralateral half will receive a combination of Platelet-Rich Plasma (PRP) and nanocross-linked Hyaluronic Acid (Luxiva). The right or left side of the face will be randomly allocated to each intervention. Simple randomization will be used for allocation. The individual patient will be considered the unit of randomization. Stratified randomization will not be performed. One appropriate method for implementing the allocation process is the use of Sequentially Numbered, Opaque, Sealed Envelopes (SNOSE). The allocation sequence will be prepared in advance, and each allocation will be placed in an opaque, sequentially numbered, and securely sealed envelope. The envelopes will be opened sequentially after the patient has met all eligibility criteria and provided informed consent, thereby ensuring appropriate allocation concealment.

Blinding (investigator's opinion)

Double blinded

Blinding description

Participants will be blinded to the intervention allocated to each side of the face. Outcome assessment will be performed by an independent assessor who is blinded to the allocation of the interventions. Due to the nature of the procedures, the treating physician cannot be blinded because of the preparation and administration of SVF and PRP. The treating physician will not be involved in outcome assessment or data analysis. Data collection and outcome assessment will be performed by blinded personnel to minimize the risk of bias.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Iran University of Medical Sciences

Street address

Iran University of Medical Sciences, Adjacent to Milad Tower, Hemmat Highway

City

Tehran

Province

Tehran

Postal code

۱۴۴۹۶۱۴۵۳۵

Approval date

2026-06-22, 1405/04/01

Ethics committee reference number

IR.IUMS.FMD.REC.1405.281

Health conditions studied

1

Description of health condition studied
Atrophic acne scars
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Severity score of atrophic acne scars
Timepoint
Assessment of atrophic acne scar severity at baseline (before intervention), 3 months after treatment and 6 months after treatment
Method of measurement
Acne Scar Grading Scale assessed by a trained clinical evaluator blinded to the intervention type on each side of the face

2

Description
Percentage of improvement in atrophic acne scars
Timepoint
Assessment of percentage of improvement in atrophic acne scars at baseline (before intervention), 3 months after treatment and 6 months after treatment
Method of measurement
Percentage of improvement in atrophic acne scars will be determined by comparison of standardized clinical photographs before and after treatment by a trained clinical evaluator blinded to the intervention type on each side of the face

Secondary outcomes

1

Description
Patient satisfaction with treatment outcome
Timepoint
Assessment of patient satisfaction with treatment outcome 6 months after intervention
Method of measurement
Patient satisfaction with treatment outcome will be assessed using a patient satisfaction questionnaire completed by the patient

2

Description
Treatment related adverse events
Timepoint
From the time of intervention until 6 months after treatmentنحوه اندازه‌گیری
Method of measurement
Based on clinical examination and recording of adverse events reported by the patient

Intervention groups

1

Description
Intervention group: Following fractional Carbon Dioxide (CO_2) laser treatment, one half of the patient's face will receive an injection of Stromal Vascular Fraction (SVF) combined with nanocross-linked Hyaluronic Acid (Luxiva; manufactured by Atra Zist Aray). The SVF will be obtained from the patient's autologous adipose tissue and, following preparation, will be combined with nanocross-linked Hyaluronic Acid and injected into the areas of atrophic acne scars.The consumable materials required for the intervention will be provided by Iran University of Medical Sciences.
Category
Treatment - Drugs

2

Description
Control group: On the opposite side of the face, following fractional carbon dioxide laser therapy, Platelet Rich Plasma combined with non cross linked hyaluronic acid will be injected. Platelet Rich Plasma will be prepared from the patient's autologous blood and, after processing, will be injected with non cross linked hyaluronic acid into areas with atrophic acne scars. This group will serve as the comparison group for evaluating the efficacy of Stromal Vascular Fraction
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Hazrat Fatemeh Educational and Therapeutic Hospital
Full name of responsible person
Fahime Sarjamei
Street address
Hazrat Fatemeh (S) Super Specialty Plastic and Reconstructive Surgery Teaching Hospital, No. 21 Street, beside Shafaq Park, Seyed Jamaleddin Asadabadi Street (Yousef Abad), Tehran, Iran.
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Majid Safa
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Iran University of Medical Sciences, Next to Milad tower, Hemmat highway
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1449614535
Phone
+98 21 8862 2703
Email
safa.m@iums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Iran 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
Fahime Sarjamei
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
Dermatology
Street address
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available