Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Comparison of the efficacy of combination therapy of Carbon Dioxide Laser Combined with Platelet-Rich Plasma versus Carbon Dioxide Laser alone in hand rejuvenation

Protocol summary

Study aim

To compare the efficacy of fractional carbon dioxide (CO2) laser combined with platelet-rich plasma (PRP) versus fractional carbon dioxide (CO2) laser alone in hand skin rejuvenation.

Design

Randomized controlled trial, with parallel groups (split_hand), double_blind, phase 2 clinical trial on 10 patients. Randomization was performed using sequentially numbered, opaque, sealed envelopes.

Settings and conduct

The trial was conducted at the dermatology clinic of Loghman Hakim Hospital. Ten patients underwent 3 sessions of fractional carbon dioxide (CO_2) laser; one hand randomly received PRP and the other received saline. Blinding was achieved using identical syringes for patients and an independent outcome assessor.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age ≥35 years Fitzpatrick skin types 1_3 Clinical evidence of photoaging Willingness and ability to comply with follow-up visits Exclusion criteria: Active infection at the treatment site Pregnancy or breastfeeding History of keloid or hypertrophic scarring Ablative laser or cosmetic procedures in the treatment area within the past 12 months

Intervention groups

Intervention group: Patients with hand wrinkles receiving combined fractional carbon dioxide (CO2) laser and platelet-rich plasma (PRP) injections on one hand. Control group: Patients with hand wrinkles receiving fractional carbon dioxide (CO2) laser and normal saline injections on the contralateral hand.

Main outcome variables

Skin wrinkle status Skin pigmentation status Skin texture status Patient satisfaction level Frequency of adverse events

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20250316065097N1**
Registration date: **2026-06-13, 1405/03/23**
Registration timing: **prospective**

Last update: **2026-06-13, 1405/03/23**
Update count: **0**

Registration date

2026-06-13, 1405/03/23

Registrant information

Name

Sanaz Zare

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 66 3322 1121

Email address

sanaz.zare@sbmu.ac.ir

Recruitment status

recruiting

Funding source

Expected recruitment start date

2026-07-06, 1405/04/15

Expected recruitment end date

2028-07-05, 1407/04/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the efficacy of combination therapy of Carbon Dioxide Laser Combined with Platelet-Rich Plasma versus Carbon Dioxide Laser alone in hand rejuvenation

Public title

Comparison of hand rejuvenation using Carbin dioxide Laser with and without platelet-rich plasma

Purpose

Other

Inclusion/Exclusion criteria

Inclusion criteria:

Mild to severe photoaging Age over 35 years Good compliance

Exclusion criteria:

Infection at the procedure site Pregnancy/Lactation History of scar and keloids History of doing ablative lasers and cosmetic procedures at the procedure site over the past year Hypersensitivity to the anesthetic agent History of coagulation disorders and consumption anticoagulant medications Uncontrolled diabetes Uncontrolled hypertension History of congenital or acquired connective tissue disorders Fitzpatrick skin type 4-6

Age

From **35 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **13**

More than 1 sample in each individual

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

PASS 11 software was used with a one-sided paired Wilcoxon Signed-Rank test to calculate the sample size. The study power was 90% and the margin of error was 5%. Using the data of the study by William et al. (Ablative fractional CO2 resurfacing for photoaging of the hands: pilot study of 10 patients), the mean and variance of the improvement in wrinkles, pigmentation, and texture of the evaluator and the patient were calculated. Considering an average of 1.5 units of desirable change in improvement, the maximum sample size based on the numbers obtained from the evaluation of the patients' wrinkle level was calculated to be 1.05±2.7 units, equivalent to 10 people.

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization will be used in this study. The unit of randomization is each hand rather than the patient; therefore, in each participant, one hand will be allocated to the intervention group (fractional CO_2 laser combined with platelet-rich plasma [PRP]) and the contralateral hand will be allocated to the control group (fractional CO_2 laser combined with normal saline). No block or stratified randomization will be performed. The random allocation sequence will be generated before the start of the study by an independent individual who is not involved in participant recruitment, treatment, or outcome assessment, using computer-generated random numbers. Based on this sequence, either the right or left hand of each participant will be assigned to the intervention group. To ensure allocation concealment, the randomization sequence will be placed in sequentially numbered, sealed, opaque envelopes. After confirmation of eligibility criteria and obtaining written informed consent, the corresponding envelope will be opened in numerical order and treatment allocation will be determined. Therefore, the investigator responsible for participant enrollment will remain unaware of the treatment assignment until allocation is completed.

Blinding (investigator's opinion)

Double blinded

Blinding description

This study was designed as a double-blind trial. The participants were blinded to the type of injectable treatment administered to each hand. Platelet-rich plasma (PRP) and normal saline were prepared in identical syringes, and injections were performed immediately after fractional CO_2 laser treatment, making it impossible for participants to distinguish between the two interventions. The outcome assessors were also blinded to the treatment allocation. Clinical photographs obtained before each treatment session and at follow-up visits were independently evaluated by two dermatologists who were unaware of the treatment assignment of each hand. The treating physician who performed the laser procedure and injections was not involved in outcome assessment or data analysis.

Placebo

Used

Assignment

Parallel

Other design features

Patients with hand wrinkle is the population of the study who referred to the skin clinic of Loghman Hakim Hospital in 1405-1407. The study method is as follows: 10 patients referred to the skin clinic of Loghman Hakim Hospital for 3 times at intervals of 4-6 weeks and after obtaining a consent form from the patient, CO2 laser is performed on both hands for all patients. PRP is injected into one hand and normal saline is injected into the other hand. Before each procedure, a photo is taken and compared and scored. The scores are about texture/wrinkles/pigmentation and overall improvement and as follows: no improvement = 0 / improvement of 25-1% = 1 / improvement of 26-50% = 2 / improvement of 51-75% = 3 / improvement of 76-100% = 4, which are reviewed blindly by two dermatologists and patients. The final follow-up of the patient is one month after the last session of PRP injection and CO2 laser. Washing Hands with soap and water and covering hands with a thin layer of local anesthetic for 20 minutes is the first stage. Then, laser is performed on both hands with parameters total fluence: 1.5 j/cm2/pulse energy: 1.5 mj/density: 9.6 watt: 30w. To prepare PRP, the patient's blood is taken and centrifuged once at 1200/10 and once at 1600/10. Then,

CO2 laser is performed on all patients and PRP is injected into one hand and normal saline is injected into the other hand. After treatment, patients are advised to use zinc oxide ointment and avoid sunlight.At the end of the study, the photos are compared blindly by two independent dermatologists and the rate of improvement is reported as a percentage from zero to one hundred. Complications such as hypopigmentation, hyperpigmentation, scarring, atrophy, and complications such as edema, pain, burning, itching, redness, blisters, bleeding, and crusting will be recorded through a questionnaire from the patients during the procedure.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Skin Research Center, Shahid Beheshti University of Medical Sciences

Street address
Skin Research Center, Shahid Beheshti University of Medical Sciences shohadae tajrish hospital ghods square shahrdari street

City
Tehran

Province
Tehran

Postal code
19839-63113

Approval date
2024-08-14, 1403/05/24

Ethics committee reference number
IR.SBMU.SRC.REC.1403.011

Health conditions studied

1

Description of health condition studied
Hand rejuvenation

ICD-10 code
L81.2

ICD-10 code description
Freckles

Primary outcomes

1

Description
Improvement in overall hand rejuvenation, assessed by change in overall hand appearance score one month after the final treatment session, evaluated by two blinded dermatologists using standardized clinical photographs.

Timepoint
One month after the final session of CO_2 laser and PRP treatment.

Method of measurement
At the end of the study, standardized clinical photographs are evaluated by two independent blinded dermatologists. Improvement is recorded as percentage change in overall hand appearance (0% = no improvement, 1–25% = mild, 26–50% = moderate, 51–75% = marked, and 76–100% = excellent improvement).

Secondary outcomes

1

Description
Improvement in hand pigmentation

Timepoint
One month after the final treatment session.

Method of measurement
Changes in hand pigmentation are assessed using standardized clinical photographs evaluated by two blinded dermatologists, and the percentage of improvement compared to baseline is recorded.

2

Description
Improvement in hand wrinkles

Timepoint
One month after the final treatment session.

Method of measurement
Wrinkle severity is evaluated by two independent blinded dermatologists using standardized photographs, and improvement is recorded as percentage reduction compared to baseline.

3

Description
Improvement in hand skin texture

Timepoint
One month after the final treatment session.

Method of measurement
Skin texture improvement is evaluated using standardized clinical photographs by two independent blinded dermatologists. Improvement is recorded as percentage change on a 0–100% scale (0% = no improvement, 100% = maximum improvement).

4

Description
Patient satisfaction with treatment

Timepoint
One month after the final treatment session.

Method of measurement
Patient satisfaction with treatment outcome is assessed using a percentage-based scale from 0 to 100%, where 0% indicates no satisfaction and 100% indicates complete satisfaction.

5

Description
Incidence of treatment-related adverse effects
Timepoint
During treatment sessions and up to one month after the final session.
Method of measurement
Treatment-related adverse effects including pain, erythema, edema, burning sensation, hyperpigmentation, hypopigmentation, infection, or scarring are recorded based on clinical examination and patient reports.

Intervention groups

1

Description
This study will be conducted as a split-hand randomized clinical trial. In each participant, both hands will be treated with ablative fractional carbon dioxide laser.First, the treatment areas will be cleansed using soap and water. A topical anesthetic cream will be applied to the skin and will be completely removed after 20 minutes.Subsequently, ablative fractional carbon dioxide laser will be performed on both hands using identical parameters:Total fluence: 1.5 joules per square centimeterPulse energy: 1.5 millijoulesDensity: 9.6Power: 30 wattsAfter laser treatment, one hand will be randomly selected to receive additional intradermal platelet-rich plasma (PRP) injection.Platelet-rich plasma (PRP) will be prepared from the patient's peripheral venous blood using a two-step centrifugation protocol with the PRP Prime kit. The first centrifugation will be performed at 1200 revolutions per minute for 10 minutes, followed by a second centrifugation at 1600 revolutions per minute for 10 minutes.Finally, 3 milliliters of platelet-rich plasma will be injected intradermally into the selected hand.Treatment sessions will be performed at 4- to 6-week intervals for each participant.
Category
Treatment - Drugs

2

Description
This study will be conducted as a split-hand randomized clinical trial. In each participant, both hands will be treated with ablative fractional carbon dioxide laser.First, the treatment areas will be cleansed using soap and water. A topical anesthetic cream will be applied to the skin and will be completely removed after 20 minutes.Subsequently, ablative fractional carbon dioxide laser will be performed on both hands using identical parameters:Total fluence: 1.5 joules per square centimeterPulse energy: 1.5 millijoulesDensity: 9.6Power: 30 wattsAfter laser treatment, the contralateral hand will receive an intradermal injection of normal saline as placebo.Treatment sessions will be performed at 4- to 6-week intervals for each participant.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Loghman Hakim Hospital
Full name of responsible person
Sanaz Zare
Street address
Skin Research Center, Shahid Beheshti Medical University, Shohada E Tajrish, Ghods Square, Shahrdari Street
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Sanaz Zare
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Tehran<, Skin Research Center, Shahid Beheshti Medical University,Shohada E Tajrish, ghods Sq, Shahrdari St
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shahid Beheshti 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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Sanaz Zare

Position

Dermatology resident at Shahid Beheshti university of Medical Sciences

Latest degree

Medical doctor

Other areas of specialty/work

Dermatology

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Sanaz Zare

Position

MD, Dermatology resident

Latest degree

Medical doctor

Other areas of specialty/work

Dermatology

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Person responsible for updating data

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Sanaz Zare

Position

MD, Dermatology resident

Latest degree

Medical doctor

Other areas of specialty/work

Dermatology

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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

De-identified individual participant data, including demographic characteristics, clinical baseline data, and outcome variables, will be available upon reasonable request after publication of the study results. Facial and hand photographs collected during the study will also be available in a de-identified format with all identifying features removed or masked. Access to the data will be granted for scientifically justified requests and after approval by the corresponding investigator. Only data related to primary and secondary outcomes will be shared. Study protocol and statistical analysis plan will also be available upon request.

When the data will become available and for how long

Data from this study will be made available starting six months after publication of the study results in a peer-

reviewed scientific journal and will remain accessible for a period of two years from the start of data availability.

To whom data/document is available

De-identified data from this study and related study documents will be available upon reasonable scientific request to researchers affiliated with academic, educational, and research institutions, as well as to industry-based researchers with legitimate research purposes. All requests will be reviewed and approved by the principal investigator. Identifiable patient data and participant photographs will remain strictly confidential and will not be shared under any circumstances.

Under which criteria data/document could be used

Access to de-identified data and study documents will be permitted solely for scientific research purposes. Data use will be restricted to statistical analyses consistent with the approved study objectives. Any commercial use, attempts to re-identify participants, or efforts to link data back to individual identities will be strictly prohibited. Requests for data access must include a proposed analysis plan and will be subject to review and approval by the principal investigator. Data use will only be allowed within the scope of the originally stated study objectives and protocol.

From where data/document is obtainable

Requests for access to study data and documents should be directed to the principal investigator. Applicants may submit their requests via the principal investigator's email address. The contact details, including the name and email address of the principal investigator, will be made available in the final study documentation. All requests will be reviewed and considered upon scientific evaluation and approval by the principal investigator.

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

Requests for access to study data and documents should be submitted in writing to the principal investigator. Upon receipt, the request will be reviewed for scientific validity and consistency with the study objectives. If necessary, the applicant may be asked to provide a detailed analysis plan and additional clarifications. The initial review process is expected to take approximately 2 to 4 weeks. Following final approval, de-identified data will be provided to the applicant. In case of rejection, the reason will be communicated in writing.

Comments