Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Evaluation of the Effectiveness of Fractional CO_2 Laser Alone Versus Combined Fractional CO_2 Laser and Q-Switched Long-Pulsed 1064 nm Laser in Hand Rejuvenation

Protocol summary

Study aim

Evaluation of the Effectiveness of Fractional CO_2 Laser Alone Versus Combined Fractional CO_2 Laser and Q-Switched Long-Pulsed 1064 nm Laser in Hand Rejuvenation

Design

This study is a split-body randomized clinical trial in which each patient serves as their own internal control. In each individual, one arm is randomly assigned to receive fractional CO_2 laser and Q-Switched Long-Pulsed Nd:YAG 1064 nm laser, and the other arm is assigned to fractional CO_2 laser. Treatment assignment is performed using a simple randomization method in Excel software, and results are reported by dermatologists according to treatment type.

Settings and conduct

This is a randomized split-body clinical trial in which each participant receives Fractional Carbon Dioxide laser treatment in one hand and a combination of Fractional Carbon Dioxide laser and Q-Switched Long-Pulsed Neodymium-Doped Yttrium Aluminum Garnet 1064 nm laser in the contralateral hand. Treatments are performed in three sessions with 4 to 6-week intervals, and outcomes are evaluated by a blinded assessor at predefined follow-up time points.

Participants/Inclusion and exclusion criteria

Exclusion criteria include active hand skin diseases, abnormal scarring history, use of photosensitizing drugs, pregnancy or lactation, psychiatric disorders or poor compliance, recent laser or similar treatments within six months, systemic or autoimmune diseases affecting wound healing, and severe photosensitivity or hypersensitivity to treatment materials.

Intervention groups

In this group, the allocated hand will receive combination therapy with Fractional Carbon Dioxide laser and Q-Switched Long-Pulsed Neodymium-Doped Yttrium Aluminum Garnet 1064 nm laser.

Main outcome variables

Overall hand skin rejuvenation improvement

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20260502069236N1**
Registration date: **2026-05-17, 1405/02/27**
Registration timing: **prospective**

Last update: **2026-05-17, 1405/02/27**
Update count: **0**

Registration date

2026-05-17, 1405/02/27

Registrant information

Name

Hasan Sharifian dorcheh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 25719

Email address

hasansh1150@gmail.com

Recruitment status

recruiting

Funding source

Expected recruitment start date

2026-05-26, 1405/03/05

Expected recruitment end date

2027-03-21, 1406/01/01

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluation of the Effectiveness of Fractional CO_2 Laser Alone Versus Combined Fractional CO_2 Laser and Q-Switched Long-Pulsed 1064 nm Laser in Hand Rejuvenation

Public title
Comparison of the effectiveness of two laser treatment methods for hand rejuvenation
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
They should have good overall health Participation should be voluntary They should have no prior history of skin disease
Exclusion criteria:
active skin diseases on the hands such as eczema, psoriasis, skin infections, or open wounds a history of abnormal scarring, including hypertrophic scars or keloids use of photosensitizing medications pregnancy or breastfeeding psychiatric disorders or inability to adhere to treatment protocols and follow-up a history of laser treatments or similar procedures on the hands within the past six months systemic or autoimmune diseases such as lupus or scleroderma that may interfere with skin healing severe allergies to light or materials used in the treatment
Age
From **45 years** old to **55 years** old
Gender
Female

Phase
N/A
Groups that have been masked

- Outcome assessor

Sample size
Target sample size: **70**
More than 1 sample in each individual
Number of samples in each individual: **2**
Each hand will be considered as one sample per individual
Randomization (investigator's opinion)
N/A
Randomization description
Blinding (investigator's opinion)
Single blinded
Blinding description
Several dermatologists, blinded to the type of laser used on each hand (CO_2 alone versus CO_2 combined with Q-switched laser), will offer their assessments concerning the comparison of the two hands
Placebo
Not used
Assignment
Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of the Skin Research Center of Shahid Beheshti University of Medical Sciences
Street address
Tehran, Qods Square, Shahrdari Street, not far from Tajrish Square, Tajrish Martyrs Medical Center, Skin Research Center
City
Tehran
Province
Tehran
Postal code
1989934148
Approval date
2026-01-07, 1404/10/17
Ethics committee reference number
IR.SBMU.SRC.REC.1404.024

Health conditions studied

1

Description of health condition studied
Hand Rejuvenation
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Change in the clinical improvement score of hand skin wrinkles based on dermatologist assessment using a four-grade clinical improvement scale.
Timepoint
Before treatment, after each treatment session, and at one month and three months following the final treatment session
Method of measurement
This variable will be assessed using both objective and subjective methods. In the objective method, standardized digital photography of both hands will be performed under fixed conditions (constant lighting, angle, distance, and uniform background). Pre- and post-treatment images will be evaluated by two independent dermatologists blinded to the treatment allocation, and the degree of improvement will be reported as a percentage ranging from 0 to 100%. Treatment response will be classified as follows: low response (0–25% improvement), mild response (25–50% improvement),

moderate response (50–75% improvement), and excellent response (greater than 75% improvement). In case of disagreement greater than one grade, a third dermatologist will be consulted. In the subjective method, patient satisfaction with treatment outcomes will be recorded through a standardized direct questionnaire. In addition, adverse events including edema, pain, erythema, pruritus, blistering, hypopigmentation, hyperpigmentation, and scarring will be assessed and documented by the treating physician at each visit.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention groIn this group, the hand allocated to the combination treatment will receive both Fractional Carbon Dioxide laser and Q-Switched Long-Pulsed Neodymium-Doped Yttrium Aluminum Garnet 1064 nm laser therapy.In each treatment session, Fractional Carbon Dioxide laser therapy will first be applied to the hand skin, followed by Q-Switched Long-Pulsed Neodymium-Doped Yttrium Aluminum Garnet laser treatment on the same area.Treatment will be performed in three sessions with intervals of 4 to 6 weeks between sessions. Prior to treatment initiation, standardized digital photography and skin analysis using the FotoFinder imaging system will be performed.Patients will be evaluated one month and three months after the final treatment session regarding the degree of hand skin rejuvenation, pigmentation changes, skin texture improvement, wrinkle reduction, and possible adverse effects.

Category

Treatment - Other

2

Description

Control group: In this group, the hand allocated to the control group will receive treatment with Fractional Carbon Dioxide laser alone.Treatment will be performed in three sessions with intervals of 4 to 6 weeks between sessions. Standardized digital photography and skin analysis using the FotoFinder imaging system will be conducted before treatment initiation.Patients will be followed one month and three months after the final treatment session, and clinical improvement, skin texture and pigmentation changes, and possible adverse effects will be evaluated and recorded.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Loghman Hakim Hospital

Full name of responsible person
Hasan Sharifian dorcheh

Street address
Tehran - Lashgar Crossroads, Special Street - Loghman Hakim Hospital

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Tehran

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loghman.hospital@sbmu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Afshin Zarghi

Street address
Tehran - Shahid Chamran Highway, Yemen Street - Shahid Arabi Street - Building No. 2 - Fifth Floor

City
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Province
Tehran

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1989934148

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info@sbmu.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
No

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
Hasan Sharifian dorcheh

Position
Resident

Latest degree
Medical doctor

Other areas of specialty/work
Dermatology

Street address
Tehran - Shariati Street - Shahrdari Street - Minoo Dead End - Skin Research Center

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Person responsible for scientific inquiries

Contact

Name of organization / entity
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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
Dermatology

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Person responsible for updating data

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Full name of responsible person
Hasan Sharifian dorcheh

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Email
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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
Yes - There is 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
Yes - There is a plan to make this available

Analytic Code
No - There is not a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document
All data is potentially shareable after de-identifying individuals.

When the data will become available and for how long
Access period starts 1 year after results are published.

To whom data/document is available
Our data will only be available to researchers working in academic and scientific institutions.

Under which criteria data/document could be used
The data and documentation of this study will be used solely for scientific and research analysis within the framework of the approved goals of the project.

From where data/document is obtainable
Hassan Sharifian Darcheh ۹۸۹۱۳۶۷۷۷۴۳۳

What processes are involved for a request to access data/document
Submitting a Formal Request: The applicant must send an official written request via the university’s institutional email to the principal investigator. The request should clearly state the purpose of use, the specific data required, and the intended application.

Preliminary Review: Upon receiving the request, the principal investigator will review it for consistency with the study's objectives and ethical considerations. If necessary, the request will be discussed with other members of the research team. Ethical Approval: If the applicant seeks access to raw or individual-level data, a valid ethical approval from an authorized ethics committee must be provided. Without such approval, data access will not be granted. Confidentiality Agreement: Once the request is approved, the applicant will be required to sign a confidentiality agreement, committing to use the data only for the declared purpose and to refrain from sharing it with unauthorized parties. Data Preparation and Anonymization: Prior to data sharing, all datasets will be anonymized and coded to ensure the confidentiality of participants. Data Delivery: The data will be delivered as an encrypted file through the official university email. Depending on the scope and volume of the request, the review and delivery process typically takes 10 to 20 working days

Comments