Clinical Trial Protocol
Iranian Registry of Clinical Trials

11 Jun 2026

Evaluation of the efficacy of fractional CO2 laser in combination with 5-fluorouracil cream compared to PDL laser in the treatment of hypertrophic and keloidal scars: A randomized controlled clinical trial

Protocol summary

Study aim
Determining the effectiveness of fractional CO2 laser in combination with 5-fluorouracil cream compared to PDL laser in the treatment of hypertrophic and keloid scars.

Design
Clinical trial with parallel groups, single-blind, randomized, phase 2 on 24 patients, simple randomization was used for randomization.

Settings and conduct
The selected patients will have at least 2 erythematous or keloid hypertrophic scar lesions, with a minimum size of 5x5 cm2 or with a length of at least 5 cm will refer to the laser center of Tehran Hazrat Fatemeh Hospital and will be subjected to one of the following treatments: 1. PDL (Pulse Dye Laser) laser treatment (control intervention)2. Fractional CO2 laser treatment in combination with 5-fluorouracil cream The treatment period for the first group is 3 sessions with an interval of 1 month and for the second one 3 sessions with an interval of 1 month with the use of 5FU cream for 5 days after each session

Participants/Inclusion and exclusion criteria
1. Age over 18 years 2. Patients with at least 2 hypertrophic scars 3. The size at least 5x5 cm square or the length is at least 5 cm 4. The patient is not pregnant or breastfeeding. 5. During the last two months, the patient has not received any treatment for the lesions 6. No diseases such as diabetes 7. The patient's cooperation in carrying out therapeutic interventions and referring for all therapeutic sessions

Intervention groups
1. Treatment with PDL (Pulse Dye Laser) (control intervention) 2. Fractional CO2 laser treatment with 5-fluorouracil cream The length of the treatment period for the first group is 3 sessions with an interval of 1 month and for the second group 3 sessions with an interval of 1 month along with the use of 5FU cream for 5 days after each treatment session.

Main outcome variables
Effectiveness of treatment; safety of treatment; Tolerability of treatment; satisfaction with treatment

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20190901044666N4**
Registration date: **2023-01-18, 1401/10/28**
Registration timing: **registered_while_recruiting**

Last update: **2023-01-18, 1401/10/28**
Update count: **0**

Registration date
2023-01-18, 1401/10/28

Registrant information

Name
Afsaneh Sadeghzadeh bazargan

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 21 6435 2421

Email address
sadeghzadeh.a@iums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-01-17, 1401/10/27

Expected recruitment end date
2023-04-16, 1402/01/27

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the efficacy of fractional CO2 laser in combination with 5-fluorouracil cream compared to PDL laser in the treatment of hypertrophic and keloidal scars: A randomized controlled clinical trial

Public title

Effect of fractional CO2 laser in combination with 5-fluorouracil cream compared to PDL laser in the treatment of hypertrophic and keloidal scars

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients over 18 years old Patients with a confirmed diagnosis of erythematous hypertrophic scar in the number of at least 2 The size of the waste should be at least 5x5 cm square or have a length of at least 5 cm The patient is not pregnant or breastfeeding During the last two months, the patient has not received any treatment for the lesions, including laser treatment, topical or injectable corticosteroids The patient has no underlying diseases that lead to scar healing process; such as diabetes or weakened immune system The patient's cooperation in carrying out therapeutic interventions and referring for all therapeutic sessions

Exclusion criteria:

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size

Target sample size: **24**

Randomization (investigator's opinion)

Randomized

Randomization description

Using the simple randomization method, the patients who refer to the laser clinic of Hazrat Fatemeh Hospital are placed in 2 groups in such a way that one envelope is randomly selected for each patient from the number of 24 sealed envelopes. Inside each envelope is the letter A or B. Group A patients will be treated with PDL laser and group B patients will be treated with fractional CO2 laser in combination with 5FU cream.

Blinding (investigator's opinion)

Single blinded

Blinding description

Due to the clear difference between the mentioned therapeutic interventions, it was not possible to blind the therapist and the patients, and as a result, the study will be conducted in a one-sided blind manner. In other words, the evaluation of the results of the studies will be done by an evaluator who is blind to the type of intervention (a dermatologist who does not know which treatment group the patient is in) and based on the images taken of the lesions in each session. Also, data analysis will be done by a blinded statistician

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

Rasoul Akram Hospital, At the corner of Mansouri St, Niayesh St, Satarkhan St

City

Tehran

Province

Tehran

Postal code

۱۴۴۵۶۱۳۱۳۱

Approval date

2022-11-23, 1401/09/02

Ethics committee reference number

IR.IUMS.FMD.REC.1401.435

Health conditions studied

1

Description of health condition studied

Hypertrophic scar

ICD-10 code

L91.0

ICD-10 code description

Hypertrophic scar

Primary outcomes

1

Description

Effectiveness of treatment on scar

Timepoint

Scar score measurement at the beginning of the study (before the start of the intervention) and after the end of the third session of the intervention (3 months later)

Method of measurement

Vancouver scar scale (VSS) scoring method will be used

to check the effectiveness of the treatment. This scale includes examination of 4 characteristics of the lesion, including: vascularity, pigmentation, height and flexibility, which are scored for each characteristic and the sum of all points will be checked in order to evaluate the improvement of the lesion.

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Fractional CO2 laser treatment in combination with 5FU cream: Before the intervention, gentle cleaning of the desired lesion will be done using gauze soaked in normal saline. Then 60 minutes before the laser treatment, local anesthetic cream containing 2.5% lidocaine and 2.5% prilocaine (Xyla-P, Tehran Chemie, Tehran, Iran) will be applied on the lesion. At the end of 60 minutes, the local anesthetic cream will be removed using alcohol cotton. Then fractional CO2 laser will be applied using Deka SmartXide DOT (Deka, Florence, Italy) laser device (with power 14, stack 2, space 600 and dwell time 600) in each lesion area of 5x5 cm2. Immediately after laser treatment, five percent 5FU cream is used in the lasered area and this treatment will continue twice a day for 5 days.

Category
Treatment - Drugs

2

Description
Control group: PDL laser treatment:Before the intervention, gentle cleaning of the desired lesion will be done using gauze soaked in normal saline. Then PDL laser using Deka Alexandrite laser device (Synchro VasQ, Deka, Florence, Italy) with spot size of 7 mm, single duration of 0.5 milliseconds and power of 7 J/cm2 with 50 shots per 5x5 lesion area Square centimeters will apply.

Category
Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center
Fatima Plastic and Reconstructive Surgery Hospital

Full name of responsible person
Mahta Mirhashemi

Street address
No. 23, West 21th Street, Yousef Abad

City
Tehran

Province
Tehran

Postal code
1433933111

Phone
+98 21 8871 7272

Email
crtfatima@ums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Iran University of Medical Sciences

Full name of responsible person
Hosein Keyvani

Street address
Iran University of Medical Sciences, Hemmat Highway, Tehran, Iran

City
Tehran

Province
Tehran

Postal code
1449614535

Phone
+98 21 8670 2503

Email
keyvani.h@ums.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
Afsaneh Sadeghzadeh bazargan

Position
Assistant Professor

Latest degree
Specialist

Other areas of specialty/work
Dermatology

Street address

Hazrate Rasoole Akram Hospital,Niayesh St,Satarkhan Av, Tehran

City
Tehran

Province
Tehran

Postal code
1445613131

Phone
+98 21 6435 2421

Fax

Email
sadeghzadeh.a@iums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Iran University of Medical Sciences

Full name of responsible person
Afsaneh Sadeghzadeh bazargan

Position
Assistant Professor

Latest degree
Specialist

Other areas of specialty/work
Dermatology

Street address
Hazrate Rasoole Akram Hospital,Niayesh St,Satarkhan Av, Tehran

City
Tehran

Province
Tehran

Postal code
1445613131

Phone
+98 21 6435 2421

Fax

Email
sadeghzadeh.a@iums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Iran University of Medical Sciences

Full name of responsible person
Afsaneh Sadeghzadeh bazargan

Position
Assistant Professor

Latest degree
Specialist

Other areas of specialty/work
Dermatology

Street address
Hazrate Rasoole Akram Hospital,Niayesh St,Satarkhan Av, Tehran

City
Tehran

Province
Tehran

Postal code
1445613131

Phone
+98 21 6435 2421

Fax

Email
sadeghzadeh.a@iums.ac.ir

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