Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Evaluation of the efficacy and safety of co2 fractional laser in combination with Pulsed dye laser vs. each one alone in treatment of hypertrophic burn scars: a blinded RCT

Protocol summary

Study aim

The main purpose: Comparing scar Improvements (total VSS score, color, vessels, flexibility) between three groups co2 fractional laser, Pulsed-Dye Laser (PDL) and co2 fractional laser plus PDL. Secondary purpose: Comparing patient satisfaction between the three groups

Design

A three-arm parallel group randomized trial with blinded secondary assessor.

Settings and conduct

The main performer (Dr. Goodarzi) performs the treatment with fractional co2 and PDL lasers. All volunteers will receive written consent and all patients who will be included in the study will receive accurate and high-quality imaging of their scars before receiving any treatment and 40 days after the last treatment. Evaluation of the results of interventions performed by a secondary assessor who is a dermatologist (Dr. Rouhani) and this study is blind on his behalf.

Participants/Inclusion and exclusion criteria

Women who are included in the study should not breastfeed; should not be pregnant. Study participants should not have used lasers for the past 1 month; should not have used topical or injectable corticosteroids in the past 1 month ; shouldn't have underlying diseases that interfere with the healing process of the scar; Like diabetes

Intervention groups

Patients with hypertrophic burn scars are divided into three groups: Group 1: PDL lasers are performed in one treatment session and repeated for up to 3 sessions. Group 2: Fractional CO2 lasers are performed in one treatment session and repeated up to 3 sessions. Group 3: Combination therapy includes one PDL laser and one fractional co2 laser, both of which are performed in one treatment session and repeated for up to 3 sessions.

Main outcome variables

1. Effectiveness in terms of scar improvement according to Vancouver Scar Scale (VSS) score 2. Safety is evaluated according to long-lasting complications.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201005048928N1**
Registration date: **2022-07-05, 1401/04/14**
Registration timing: **retrospective**

Last update: **2022-07-05, 1401/04/14**
Update count: **0**

Registration date

2022-07-05, 1401/04/14

Registrant information

Name

maedeh Karimi Kivi

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-02-27, 1399/12/09

Expected recruitment end date

2021-05-09, 1400/02/19

Actual recruitment start date

2021-02-27, 1399/12/09

Actual recruitment end date
2022-07-01, 1401/04/10
Trial completion date
2022-07-01, 1401/04/10

Scientific title
Evaluation of the efficacy and safety of co2 fractional laser in combination with Pulsed dye laser vs. each one alone in treatment of hypertrophic burn scars: a blinded RCT

Public title
Evaluation of the effect and safety of fractional PDL and CO2 lasers on burn scars
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
All patients with hypertrophic scars caused by burn
Exclusion criteria:
Women who are included in the study should not breastfeed Women who are included in the study should not be pregnant Study participants should not have used lasers for the past 1 month. Study participants should not have used topical or injectable corticosteroids in the past 1 month Study participants shouldn't have underlying diseases that interfere with the healing process of the scar; Like diabetes
Age
From **10 years** old to **60 years** old
Gender
Both

Phase
3
Groups that have been masked

- Outcome assessor

Sample size
Target sample size: **60**
More than 1 sample in each individual
Number of samples in each individual: **3**
بسته به میزان وسعت سوختگی در بیماران، از بعضی از آنان بیش از یک نمونه گرفته شده است.
Actual sample size reached: **55**
More than 1 sample in each individual
Actual sample size in each individual: **3**
بسته به میزان وسعت سوختگی در بیماران، از بعضی از آنان بیش از یک نمونه گرفته شده است.
Randomization (investigator's opinion)
Randomized
Randomization description
The randomization method is to prepare a random list in the form of random blocks with a volume of 60 that patients are divided into three groups (2 intervention groups and a control group). The random list will be generated by the statistician of the project and will be provided directly to the main executor of the project. It should be noted that the patient randomization list is prepared by NCSS PASS11. Using the Procedures menu, the DOE submenu and select the desired method in the Randomization list will be done.
Blinding (investigator's opinion)
Single blinded
Blinding description
The present study is a clinical trial study with three arms and one blind side. The main performer (Dr. Godarzi) performs the treatment for patients with fractional co2 lasers or PDL lasers or a combination of both treatments depending on the group of patients in which the patient is placed. The results of the interventions are evaluated by a secondary assessor who is a dermatologist (Dr. Rouhani) and she is blind in this study.
Placebo
Not used
Assignment
Factorial
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
Hemmat Highway between Chamran and Sheikh Fazlollah, Iran University of Medical Sciences, 5th Floor
City
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Tehran
Postal code
1449614535
Approval date
2020-09-22, 1399/07/01
Ethics committee reference number
IR.IUMS.FMD.REC.1399.411

Health conditions studied

1

Description of health condition studied
treatment of hypertrophic or keloidal burn scars
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Effectiveness of co2 laser fractional + PDL laser vs each one alone in terms of scar improvement
Timepoint
Before starting treatment, 40 days after the last treatment session

Method of measurement
Due to the Total Vancouver Scar Scale, color of the scar, vascular distribution of the scar, flexibility of the scar, height of the scar

2

Description
CO2 fractional laser + PDL safety in comparison with each alone in terms of scar improvement
Timepoint
40 days after the last treatment session
Method of measurement
Prolonged pain or burning, prolonged redness or erythema, post-inflammatory hyperpigmentation (PIH) and even laser site infection

Secondary outcomes

1

Description
Patient's satisfaction with the outcome of treatment
Timepoint
40 days after the last visit
Method of measurement
questionnaire

Intervention groups

1

Description
Control group: Patients in the control group receive a PDL laser with a pulse of 595 nm in first treatment session and this treatment is repeated for up to 3 sessions. The interval between treatment sessions is about 1 month. PDL is performed using the Synchro VasQ laser device, which is made in Italy for deka Alexandrite Company. The device settings are as follows:pulse= 595 nm, power=6.5 J/cm², single duration=0.5 ms , spot size=7mm
Category
Treatment - Other

2

Description
Intervention group 1: Fractional CO2 lasers are performed in first treatment session and repeated up to 3 sessions. The interval between treatment sessions is about 1 month. Fractional Co2 is made using the smartxide2 DOT / RF, both of which are made in Italy for deka Alexandrite. The device settings are as follows: Co2 fractional laser: fractional power =12 J/cm², pulse= 10600 nm, Stack=2 , DT(dwelling time)=800 ms , space=800mm
Category
Treatment - Other

3

Description
Intervention group 2: Combination therapy includes a PDL laser and a fractional co2 laser, both of which are performed in first treatment session and repeated up to 3 sessions. The interval between treatment sessions is about 1 month. PDL is performed using a Synchro VasQ laser and Co2 fractional laser using a smartxide2 DOT / RF device, both of which are made for Deka Alexandria, Italy. The device settings are as follows: Co2 fractional laser: fractional power =12 J/cm² pulse= 10600 nm, Stack=2 , DT(dwelling time)=800 ms , space=800mm² PDL: pulse= 595 nm, power=6.5 J/cm², single duration=0.5 ms , spot size=7mm
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Hazrat Fatemeh Hospital
Full name of responsible person
Azadeh Goodarzi
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21st St., Seyed Jamaleddin Asadabadi Ave; Yousef Abad; Tehran; Iran
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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

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

Maedeh Karimi Kivi

Position

intern of medcine

Latest degree

Medical doctor

Other areas of specialty/work

General Practitioner

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Person responsible for scientific inquiries

Contact

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Position

Professor

Latest degree

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Person responsible for updating data

Contact

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Iran University of Medical Sciences

Full name of responsible person

Maedeh Karimi Kivi

Position

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Latest degree

Medical doctor

Other areas of specialty/work

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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

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

Potential data is sharing after making people undetectable

When the data will become available and for how long

One year after the results have been published

To whom data/document is available

only for academic and scientific researchers

Under which criteria data/document could be used

The data can be used for scientific researches .

From where data/document is obtainable

Maedeh Karimi Kivi, medical student, maedeh.karimi100@yahoo.com

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

After reviewing by the project executor and in consultation with the biostatistics specialist and by keeping the patients' information confidential, the applicant will be provided.

Comments