# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

02 Jun 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 Ṡtudy 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**
Tehran
**Province**
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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## Sponsors / Funding sources

**1**

**Sponsor**
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**Full name of responsible person**
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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

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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**