

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

The effect of early fractional CO2 Laser in post surgical incision treatment in patients

Protocol summary

Study aim

The effect of early carbon dioxide laser in post surgical incision treatment in plastic surgeries

Design

including 20 patients with parallel groups who were candidates for cosmetic surgery with incisions on both sides of the body. For each patient, one side is co2 lasered and the other side is left alone. Randomization to choose the laser side will be done using a table of random numbers. If a couple comes, the right side will be lasered, and if an individual comes, the left side will be lasered. After that, for double blinding, the laser prop will be placed on both sides so that the patient does not notice. Also, after six months of examining the patients, the evaluator and the examiner are not aware of the lasered side.

Settings and conduct

Patients in the laser department of Hazrat Fatemeh Hospital in two stages, including the first week and the fourth week after the surgery, are subjected to intervention for the surgical incision site with a carbon dioxide laser, and due to the double-blind nature of the study, the laser prop is applied to both sides of the surgical site. then six months after the completion of the laser, they are examined by other doctors and evaluated with the VSS criteria, and the results are analyzed by other people.

Participants/Inclusion and exclusion criteria

Inclusion criteria; Cosmetic surgery for both sides of the body or surgical incisions longer than fifteen centimeters
Exclusion criteria; Existence or history of skin disease

Intervention groups

The intervention group includes patients who are candidates for plastic surgery who have undergone surgery that had incisions on both sides of the body, and their surgical incisions were performed in two stages; In the first and fourth week after surgery, CO2 laser was used to check the effect of scar reduction.

Main outcome variables

Pigmentation Vascularity Pliability Height By the Vancouver scar scale

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230412057887N1**

Registration date: **2023-06-26, 1402/04/05**

Registration timing: **registered_while_recruiting**

Last update: **2023-06-26, 1402/04/05**

Update count: **0**

Registration date

2023-06-26, 1402/04/05

Registrant information

Name

abbas nasiri golibeghloo

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 6522 4891

Email address

abbas.nas57@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-04-24, 1402/02/04

Expected recruitment end date

2023-10-26, 1402/08/04

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of early fractional CO2 Laser in post surgical incision treatment in patients

Public title

Laser effect on surgical incision site

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Cosmetic surgery with incisions on both sides of the body or incisions larger than 15 cm

Exclusion criteria:

History or current skin disease

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size

Target sample size: **20**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomized To select people for laser surgery on the left or right side, it is done using a table of random numbers, if an even number occurs for them, the laser will be on the right side, and for those with an odd number, the laser will be on the left side.

Blinding (investigator's opinion)

Double blinded

Blinding description

Patient ; In bilateral incisions, on both sides and in incisions larger than fifteen centimeters, the laser prop is placed on the entire incision so that the patient does not notice the direction of the laser part. Evaluating doctors; Other doctors, when the patient goes to them and conducts a clinical examination and compares the incisions on both sides, or compares the left side with the right side of the wound based on the vss table, points are given without knowing the lasered and non-laser side. analyzer; The person who analyzes the tables and statistics does not know the side that was lasered for each patient

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

Tehran , highway hemmat , Next to Milad Tower , Iran university of medical science

City

Tehran

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Tehran

Postal code

1449614535

Approval date

2021-06-14, 1400/03/24

Ethics committee reference number

IR.IUMS.FMD.REC.1400.198

Health conditions studied**1****Description of health condition studied**

Plastic Surgery

ICD-10 code

Z41.1

ICD-10 code description

Encounter for cosmetic surgery

Primary outcomes**1****Description**

Pigmentation

Timepoint

Six month after laser

Method of measurement

The Vancouver scar scale

Secondary outcomes**1****Description**

Vascularity

Timepoint

Six months after laser

Method of measurement

The Vancouver scar scale

2**Description**

Pilability

Timepoint

Six months after laser

Method of measurement

The Vancouver scar scale

3**Description**

Height of Scar

Timepoint

Six months after laser

Method of measurement

The Vancouver scar scale

Intervention groups**1****Description**

Intervention group: In this group, there are 20 patients who, after bilateral cosmetic surgery (a surgery that leaves scars on both sides of the body), are lasered in two stages of their surgical incision by fractional CO2 laser, so that its effect can be compared with the other side, which is healed naturally. . This intervention in two stages; It will be done in the first and fourth week after surgery. During the laser, the laser prop is placed on all incisions so that the patient does not notice the direction of the laser. After six months, the patient is examined in the clinic and the scar condition of the incisions is compared.

Category

Treatment - Other

2**Description**

Control group: In this group, there are 20 patients who, after bilateral cosmetic surgery (a surgery that leaves scars on both sides of the body), were only touched by the laser probe in the two stages of the surgery, and the laser was not performed on the other side, which healed naturally. This intervention in two stages; It will be done in the first and fourth week after surgery. During the laser, the laser prop is placed on all incisions so that the patient does not notice the direction of the laser. After six months, the patient is examined in the clinic and the scar condition of the incisions is compared.

Category

Treatment - Other

Recruitment centers**1****Recruitment center****Name of recruitment center**

Fatima hospital

Full name of responsible person

Abbas Nasiri

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Iran University of Medical Sciences

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

Abbas Nasiri

Position

Assistant professor

Latest degree

Subspecialist

Other areas of specialty/work

Plastic surgery

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Full name of responsible person

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Position

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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

Not applicable

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

Not applicable

Data Dictionary

Not applicable