

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jun 2026

Comparison of the efficacy and safety of Low-Fluence Q-Switched 1,064 nm Nd:YAG Laser and Low-Fluence CO2 Fractional Laser for treatment of melasma in patients referred to Shohada-e Tajrish hospital during 2012 :A Randomized Controlled Split-Face Study

Protocol summary

Summary

Background: Melasma treatment remains challenging despite various laser systems available, because of potential side-effects and high recurrence rates. Aim: to Compare the efficacy and safety of Low-Fluence Q-Switched 1,064 nm Nd:YAG Laser and Low-Fluence CO2 Fractional Laser in the treatment of melasma. Method: 50 patients will be treated with Low-Fluence Q-Switched 1,064 nm Nd:YAG Laser on one side of the face and Low-Fluence CO2 Fractional Laser on the other side. Each patient will undergo laser therapy for 5 sessions every two week. The outcome will be evaluated periodically each session using the Melasma Area and Severity Index score and Melanin Index score. Follow up will be taken until 2 months after last session. Results will be analyzed and reported in the tables and diagrams.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201201318146N2**
Registration date: **2012-08-27, 1391/06/06**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2012-08-27, 1391/06/06

Registrant information

Name

Mohammadreza Razaghi

Name of organization / entity

Laser application in medical sciences research center

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Recruitment status

Recruitment complete

Funding source

laser application in medical science research center

Expected recruitment start date

2012-08-12, 1391/05/22

Expected recruitment end date

2013-08-13, 1392/05/22

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the efficacy and safety of Low-Fluence Q-Switched 1,064 nm Nd:YAG Laser and Low-Fluence CO2 Fractional Laser for treatment of melasma in patients referred to Shohada-e Tajrish hospital during 2012 :A Randomized Controlled Split-Face Study

Public title

Comparison of the efficacy and safety of two different lasers in the treatment of melasma

Purpose

Treatment

Inclusion/Exclusion criteria

All patients suffering from melasma that referred for treatment in during 2012 to the shohada-e tajrish treatment center form the study population. Study

inclusion criteria: -Age between 18 to 85 years old - Fitzpatrick skin type I-V - symmetric distribution of melasma the in both sides of patient's face study
exclusion criteria: -usage of pigment reducing topical treatments 2 weeks prior to the study -usage of peeling agents 2 weeks prior to the study -laser therapy for melasma 1 month prior to the study -a history of poor wound healing, or abnormal scarring -pregnancy or breast feeding -history of keloid -high exposure to sunlight or UV light 1 month prior to the study - concurrent active herpes simplex lesion of the skin - suspected hypersensitivity to lidocaine -bleeding disorders

Age

From **18 years** old to **85 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Shahid Beheshti university of medical sciences

Street address

Daneshjo Blvd, Velenjak, Tehran, Iran

City

tehran

Postal code

Approval date

2012-06-10, 1391/03/21

Ethics committee reference number

119

Health conditions studied

1

Description of health condition studied

melasma

ICD-10 code

L81.1

ICD-10 code description

Chloasma

Primary outcomes

1

Description

Melanin Index

Timepoint

After laser therapy

Method of measurement

Multi Probe adaptor

Secondary outcomes

empty

Intervention groups

1

Description

Each side of face is being numbered by cream lidocain 30 minutes before starting the procedure. In one side of the face, Q-Switched ND:YAG 1,064 laser with 1.5-2 j/cm² fluence and 7 mili meter spot size is being used.

Category

Treatment - Other

2

Description

In the other side, the Low-Power Fractional CO₂ laser with 1 j enery and 0.7 density is being used.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Laser application in medical sciences research center

Full name of responsible person

Street address

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Saadi Banar

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Daneshjoo Blvd, Velenjak St, Tehran, Iran

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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

Shahid Beheshti University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

empty

Person responsible for general inquiries**Contact****Name of organization / entity**

Laser application in medical sciences research center

Full name of responsible person

Niloofer Jalali

Position

MD

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Web page address**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty