Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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

Country

Iran (Islamic Republic of)

Phone

+98 21 2271 8021

Email address

laser.cntr@sbmu.ac.ir

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 numbed 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

Street address
Daneshjoo Blvd, Velenjak St, Tehran, Iran
City
Tehran
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 aplication in medical sciences research center
Full name of responsible person
Niloofar Jalali
Position
MD
Other areas of specialty/work
Street address
Shohada Tajrish medical center, Tajrish Sq
City
Tehran
Postal code
Phone
+98 21 2274 9221
Fax
Email
niloofar.jalaly@yahoo.fr
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Laser aplication in medical sciences research center
Full name of responsible person
Behrooz Barikbin
Position
Dermatologist
Other areas of specialty/work
Street address
Shohada Tajrish Medical center, Tajrish Sq
City
Tehran
Postal code
Phone
+98 21 2274 9221
Fax
Email
bbarikbin@yahoo.com
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Laser aplication in medical sciences research center
Full name of responsible person
Niloofar Jalali
Position
MD
Other areas of specialty/work
Street address
Shohada Tajrish medical center, Tajrish Sq
City
Tehran
Postal code
Phone
Fax
Email
niloofar.jalaly@yahoo.fr
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