

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Jun 2026

Comparison of the efficacy and safety of Q-Switch 1,064 nm Nd:YAG Laser with and without carbon photo enhancer lotion on reducing skin pigmentation in patients with Melasma referred to Skin and Stem cell research center of Tehran University of Medical Sciences

Protocol summary

Summary

High prevalence of melasma and its great psychological impact necessitates an efficacious, economic and safe therapeutic option. The aim of this study is to evaluate the efficacy and safety of topical carbon application with Q-switched neodymium-doped yttrium aluminium garnet (Nd:YAG) 1064 nm laser in the treatment of melasma. Methods: in this prospective trial, symmetric melasma lesions of 43 patients age between 18 and 85 years old are randomly divided into two parts to receive Nd:YAG laser with exogenous topical carbon application on a half while the other half receive Nd:YAG laser alone. The Nd:YAG laser will be used with the following parameters: fluence= 1.5-2 Joules per centimeter, spot size= 7 Millimeters. The treatment protocol consists of 6 sessions, 3 sessions with one-week intervals and 3 other sessions with 2-week intervals. The main outcomes will be assessed by colorimeter, Mexameter, and calculating the modified Melasma Area and Severity Index. The side effects and the degree of patients' satisfaction will also be recorded. Statistical analysis will be performed using statistical software.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201308181159N9**
Registration date: **2013-10-19, 1392/07/27**
Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2013-10-19, 1392/07/27

Registrant information

Name

Mohamad Ali Nilforoushzadeh

Name of organization / entity

Skin and Stem Cell Research Center, Tehran
University of Medical sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 2220 5158

Email address

sdLrc@mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Tehran University of Medical Sciences

Expected recruitment start date

2013-12-22, 1392/10/01

Expected recruitment end date

2015-02-20, 1393/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the efficacy and safety of Q-Switch 1,064 nm Nd:YAG Laser with and without carbon photo enhancer lotion on reducing skin pigmentation in patients with Melasma referred to Skin and Stem cell research center of Tehran University of Medical Sciences

Public title

Comparison of efficacy of laser Q-Switch 1,064 nm Nd:

YAG with two different methods in the treatment of Malasma

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Age between 18 and 85 years old; Fitzpatrick skin type I-V; symmetric distribution of melasma the in both sides of patient's face; 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, and solarium usage one month prior to the treatment.

Age

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

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **43**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

According to this topic that patients with symmetric damages on the face will be entered into the study, right or left part of the face will randomly receive carbon solution through laser.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Tehran University of Medical Sciences

Street address

Tehran University of Medical Sciences, Enghelab Street, Tehran, Iran

City

Tehran

Postal code

Approval date

2013-07-21, 1392/04/30

Ethics committee reference number

92-01-150-22588-89288

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

Before laser therapy

Method of measurement

Multi Probe adaptor

Secondary outcomes

empty

Intervention groups

1

Description

Laser group with topical carbon: one half of face (A side) receives 3 sessions of Nd:YAG laser (fluence= 1.5-2 Joules per centimeter, spot size=7 Millimeters) with topical carbon at 1-week intervals followed by 3 same sessions at 2-week intervals.

Category

Other

2

Description

Laser group without topical carbon: In the other side (B group), the same laser therapy will be administered at one half of face receives 3 sessions of Nd:YAG laser (fluence=1.5-2 Joules per centimeter, spot size=7 Millimeters) without topical carbon at 1-week intervals followed by 3 same sessions at 2-week intervals.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Clinics of Skin and Stem cell Research Center of Tehran University of Medical Sciences

Full name of responsible person

Elham Rahimi

Street address

No 4, Maryam Alley, South Kamraniyeh Street,
Tehran, Iran

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research, Tehran University of
Medical Sciences

Full name of responsible person

Masoud Younesian

Street address

Vice Chancellor for Research, Tehran University of
Medical Sciences, Enghelab Street, 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

Vice Chancellor for Research, Tehran 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

Skin and Stem cell Research Center of Tehran
University of Medical Sciences

Full name of responsible person

Elham Rahimi

Position

General Practitioner

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Skin and Stem cell Research Center of Tehran
University of Medical Sciences

Full name of responsible person

Mohammad Ali Nilforoushzadeh

Position

Dermatologist

Other areas of specialty/work

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Web page address

Person responsible for updating data

Contact

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