

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

Comparison of combination of Q-switch Nd:YAG laser and microdermabrasion , with Q-switch Nd:YAG laser alone in treatment of melasma

Protocol summary

Study aim

The purpose of the study is to determine if combination of microdermabrasion and Q-switched Nd:YAG laser, produced significant improvement of melasma when compared with Q-switched Nd:YAG laser alone.

Design

This is a non-blind randomized clinical trial with a split-face design and parallel groups with 30 subjects.outcome assessment is going to be done blindly.Randomization is by use of permuted block randomization.

Settings and conduct

Patients come to the Niyusha clinic every month and each session undergo microdermabrasion on half of their faces (that will be chosen randomly) and a laser beam therapy for both sides of their faces using 1064 nm Q-switch Nd-YAG laser.

Participants/Inclusion and exclusion criteria

Inclusion criteria is women and men older than 18 years with bilateral moderate or severe melasma. Exclusion criteria includes pregnancy , breast feeding ,use of any 4% hydroquinone formulation within 3 months of entry , history of chemical peels , microdermabrasion or facial laser treatment within 9 months of entry.

Intervention groups

This is going to be a split-face study and for each patient,one half of face will be test and the other half will be the control.The side allocated randomly to receive microdermabrasion prior to laser therapy , was treated with a total of 3 pass in each session at the following visits : baseline , month 1 , month 2 and month 3.The face was then rinsed with water and dried and immediately both sides of patient's face was treated with Q-switched Nd:YAG laser (1064 nm) with fluences of 2.5 -6.5 J/cm² with a 4 or 6 mm spot ,using only 2 laser passes to achieve complete coverage of the affected skin.

Main outcome variables

Melasma Area and Severity Index (MASI) ; Physician Global melasma improvement Assessment (PhGA) ; Patient Global melasma improvement Assessment (PGA) ;

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191228045917N2**
Registration date: **2020-09-20, 1399/06/30**
Registration timing: **prospective**

Last update: **2020-09-20, 1399/06/30**

Update count: **0**

Registration date

2020-09-20, 1399/06/30

Registrant information

Name

Parvaneh Hatami

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 5560 9951

Email address

p-hatami@alumnus.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-10-06, 1399/07/15

Expected recruitment end date

2021-01-04, 1399/10/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of combination of Q-switch Nd:YAG laser and microdermabrasion , with Q-switch Nd:YAG laser alone in treatment of melasma

Public title

laser and microdermabrasion in melasma

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

women and men older than 18 years with bilateral moderate or severe melasma clinically diagnosed by a dermatologist

Exclusion criteria:

pregnancy breast feeding use of any 4% hydroquinone formulation within last 3 months history of chemical peels microdermabrasion or facial laser treatment within last 9 months

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **30**

More than 1 sample in each individual

Number of samples in each individual: **2**

lesions in each side of individual's face are considered as one sample.

Randomization (investigator's opinion)

Randomized

Randomization description

For random allocation of two types of treatment (laser with or without microdermabrasion), at first, face of subject is divided to 2 parts (right and left), then we generate 30 (number of our subjects) random samples with block randomization with considering 2 treatments and 4, 6 and 8 blocks. Finally, we consider one side of face (that is chosen randomly) constant and based on random sequence generated, allocate the treatment with laser and microdermabrasion to that side of face. It is obvious that the other side will undergo treatment with laser alone. For generation of random sequence, we will use an online software with this address:

<https://www.sealedenvelope.com/simple-randomiser/v1/lists>

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features

This study is going to be done as a split-face study. So each patient will be its own control

Secondary Ids

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Rafsanjan university of medical sciences

Street address

Emam Ali Blv. Central building

City

Rafsanjan

Province

Kerman

Postal code

7717933777

Approval date

2016-03-13, 1394/12/23

Ethics committee reference number

IR.RUMS.REC.1394.279

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

Melasma

ICD-10 code

L81.1

ICD-10 code description

Chloasma

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

Melasma Area and Severity Index (MASI) score ; Physician Global melasma improvement Assessment (PhGA) score ; Patient Global melasma improvement Assessment (PGA) score

Timepoint

baseline, 12 week, 16 week, 32 week

Method of measurement

Photographic evaluation by dermatologist- general assessment of the patient-asking from patients

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The side allocated to receive microdermabrasion prior to laser therapy, is treated with a total of 3 pass in each session at the following visits: baseline, month 1, month 2 and month 3. After degreasing with alcohol and waiting for the skin to dry, 3 pass microdermabrasion is done using 6 mm head and 400 mmHg pressure to achieve mild erythema. After washing with water and drying, treatment with Q-switched Nd:YAG laser (1064 nm) with fluences of 2.5 -6.5 J/cm² with a 4 or 6 mm spot, using 2 laser passing will be done.

Category

Treatment - Other

2

Description

Control group: The other side of face is treated with Q-switched Nd:YAG laser (1064 nm) with fluences of 2.5 -6.5 J/cm² with a 4 or 6 mm spot, using 2 laser passing.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Niyusha clinic

Full name of responsible person

Dr Parvaneh Hatami

Street address

No 180, 11th street, Gisha street, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1447683378

Phone

+98 21 8824 2020

Email

p_hatami2001@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran's national elites foundation

Full name of responsible person

Dr Alireza Saeedi

Street address

No 209, Tahernia Av. Azadi St. Tehran, Iran

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Postal code

1457893111

Phone

+98 21 6347 8000

Email

p_hatami2001@yahoo.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Iran's national elites foundation

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

Other

Person responsible for general inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Parvaneh Hatami

Position

researcher

Latest degree

Specialist

Other areas of specialty/work

Dermatology

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

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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

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All patient information can be shared without naming and identifying them

When the data will become available and for how long

Details of the data are immediately available after publishing the results

To whom data/document is available

All researchers and health professionals working in academic ,scientific and medical institutions.

Under which criteria data/document could be used

The data is only shared for person whose purpose is to improve the therapeutic course of Melasma

From where data/document is obtainable

Niyusha clinic.Dr Parvaneh Hatami .Dermatologist.No

180,11th St.Gisha

St.tehran,Iran.09123137987.p_hatami2001@yahoo.com

What processes are involved for a request to access data/document

Information is available immediately after verifying that the applicant's circumstances are met by the competent authorities

Comments**Person responsible for updating data****Contact****Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Parvaneh Hatami

Position

researcher

Latest degree

Specialist

Other areas of specialty/work

Dermatology

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