

# 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/cm<sup>2</sup> 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/cm<sup>2</sup> 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/cm<sup>2</sup> 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

##### City

Tehran

##### Province

Tehran

##### 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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No 180, 11th St., Gisha St.

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## Person responsible for scientific inquiries

#### Contact

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Tehran University of Medical Sciences

##### Full name of responsible person

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**Latest degree**

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**Email**

p\_hatami2001@yahoo.com

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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**

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