

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

04 Jun 2026

### Comparison of the efficacy of laser Q-switch 1064 ND:YAGR and erbium laser on the Hyperpigmentation of Macular Amyloidosis

#### Protocol summary

##### Study aim

Access to efficient treatment, low side effects and rapid responses in improvement of macular amyloidosis disease

##### Design

The aim of this study was to achieve high efficacy, low side effects and rapid response to improvement of macular amyloidosis. Thirty patients were studied and the areas of dark-spotted skin were divided into three separate regions in each patient, two areas treated with two different types of lasers, and one area as a control group did not receive any treatment.

##### Settings and conduct

Before laser therapy, photography and skin analysis are performed with a calorimeter and mexameter device. and dark skin lesions of each patient divided into 3 region. A: Dark skin patches will be operated under treatment by laser Q-switch 1064 ND:YAGR alone. B: Dark skin patches will be operated under treatment by pilling microlaser through Fractional Erbium short pulse and Q-Switch 1,064 nm Nd:YAG Laser at the same time. C: Dark skin patches will be defined as a control group with any treatment. Every patient will be under laser treatment for 3 session with 4 weeks interval at the skin and stem cell research center. Result evaluation and comparison will be done by calorimeter and mexameter.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria include: Age more than 16 and less than 60; Skin phenotype between 3-5; Lack of inheritance and hormonal or malignant skin diseases. Exclusion criteria include: Using any drug related to decreasing pigment during last 2 weeks; No Solarium during last month, No pregnancy and breastfeeding.

##### Intervention groups

First intervention group: Region of laser Q-switch Nd:YAG, 1064 (part A) Second intervention group: Laser region by Q-switch Nd:YAG, 1064 and Fractional Erbium (part B) And the third group: that does not receive any treatment as the control zone.(part G)

#### Main outcome variables

Melanin Index; side effects; patient's satisfaction

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20080901001159N23**

Registration date: **2019-05-25, 1398/03/04**

Registration timing: **retrospective**

Last update: **2019-05-25, 1398/03/04**

Update count: **0**

##### Registration date

2019-05-25, 1398/03/04

##### 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

sdllrc@mui.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

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

##### Expected recruitment start date

2014-03-21, 1393/01/01

##### Expected recruitment end date

2015-03-21, 1394/01/01

**Actual recruitment start date**

2015-03-21, 1394/01/01

**Actual recruitment end date**

2018-05-22, 1397/03/01

**Trial completion date**

2018-08-23, 1397/06/01

**Scientific title**

Comparison of the efficacy of laser Q-switch 1064 ND:YAGR and erbium laser on the Hyperpigmentation of Macular Amyloidosis

**Public title**

Treatment of Hyperpigmentation skin on Macular Amyloidosis patient with using two different types of lasers

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Age more than 16 and less than 60 Skin phenotype between 3-5 lack of acute infection in part of body which is under laser treatment Lack of inheritance and hormonal or malignant skin diseases

**Exclusion criteria:**

Using any drug related to decreasing pigment during last 2 weeks Laser therapy in order to treat macular during last 1 month No Solarium during last month No pregnancy and breastfeeding.

**Age**From **16 years** old to **60 years** old**Gender**

Both

**Phase**

3

**Groups that have been masked***No information***Sample size**Target sample size: **30**Actual sample size reached: **30****Randomization (investigator's opinion)**

Not randomized

**Randomization description****Blinding (investigator's opinion)**

Not blinded

**Blinding description****Placebo**

Not used

**Assignment**

Parallel

**Other design features****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

**Province**

Tehran

**Postal code**

1417653761

**Approval date**

2014-02-17, 1392/11/28

**Ethics committee reference number**

92-02-150-22574-101834

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

Macular amyloid

**ICD-10 code**

L99.0

**ICD-10 code description**

Amyloidosis of skin

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

Melanin Index

**Timepoint**

Before and after laser therapy

**Method of measurement**

Multi Probe adaptor

**Secondary outcomes**

empty

**Intervention groups****1****Description**

Region of laser Q-switch Nd:YAG, 1064 nanometer: On the one side of the macular or (partA) , three sessions with four weeks intervals will be treated with with laser Q-switch Nd:YAG, 1064 nanometer with flounce equal to 700-1200 Joules per centimeter

**Category**

Treatment - Devices

**2****Description**

Laser region by Q-switch and microlaser pilling: In the second intervention group, another part of disaster region (part B), simultaneously for three sessions at intervals of four weeks, will be operated under treatment

with laser Q-switch Nd: YAG and microlaser pilling

**Category**

Treatment - Devices

**3**

**Description**

Control Group: G region defined in disorder, as the control group does not receive any treatment

**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**

Sara Zolghadr

**Street address**

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

**City**

Tehran

**Province**

Tehran

**Postal code**

1937957511

**Phone**

+98 21 2221 5558

**Email**

nilforoosh@sina.tums.ac.ir

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

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

**Full name of responsible person**

Mohammad Ali Nilforoushzadeh

**Street address**

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

**City**

Tehran

**Province**

Tehran

**Postal code**

1937957511

**Phone**

+98 21 2221 5558

**Email**

nilforoosh@sina.tums.ac.ir

**Grant name**

**Grant code / Reference number**

**Is the source of funding the same sponsor**

**organization/entity?**

Yes

**Title of funding source**

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

**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**

Academic

**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**

Sara Zolghadr Elizei

**Position**

Dermatologist

**Latest degree**

Specialist

**Other areas of specialty/work**

Dermatology

**Street address**

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

**City**

Tehran

**Province**

Tehran

**Postal code**

1937957511

**Phone**

+98 21 2220 1710

**Fax**

**Email**

saraz85182@hotmail.com

**Web page address**

**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

**Latest degree**

Specialist

**Other areas of specialty/work**

Dermatology

**Street address**

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

**City**

Tehran

**Province**

Tehran

**Postal code**

1937957511

**Phone**

+98 21 2220 1710

**Fax****Email**

nilforoosh@sina.tums.ac.ir

**Web page address****City**

Tehran

**Province**

Tehran

**Postal code**

1937957511

**Phone**

+98 21 2220 1710

**Fax****Email**

mmahoodbeyk@yahoo.com

**Web page address****Person responsible for updating data****Contact****Name of organization / entity**

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

**Full name of responsible person**

Mona Mahmoudbeyk

**Position**

Research manager

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Reproductive Biology

**Street address**

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

**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

**Justification/reason for indecision/not sharing IPD**

No more information

**Study Protocol**

Undecided - It is not yet known if there will be a plan to  
make this available

**Statistical Analysis Plan**

Not applicable

**Informed Consent Form**

Undecided - It is not yet known if there will be a plan to  
make this available

**Clinical Study Report**

Undecided - It is not yet known if there will be a plan to  
make this available

**Analytic Code**

Not applicable

**Data Dictionary**

Not applicable