

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

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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

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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

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

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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

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Mohammad Ali Nilforoushzadeh

Position

Dermatologist

Latest degree

Specialist

Other areas of specialty/work

Dermatology

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Skin and Stem cell Research Center of Tehran
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Full name of responsible person

Mona Mahmoudbeyk

Position

Research manager

Latest degree

Ph.D.

Other areas of specialty/work

Reproductive Biology

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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