

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

Comparative study of 1064nm Q-switched ND:YAG laser and Er:YAG2940nm laser in treatment of macular amyloidosis

Protocol summary

Study aim

Determining and comparing the effectiveness of Q-switched laser Nd: YAG 1064nm and Er: YAG 2940nm in the treatment of macular amyloidosis.

Design

The study is a randomized clinical trial of a "non-inferiority" that will be performed on 39 patients referred to dermatological clinic with a clinical diagnosis of macular amyloidosis. Excel software Rand function will be used for randomization.

Settings and conduct

This study will be performed on patients with clinical signs of macular amyloidosis referred to the dermatology clinic of Al-Zahra Hospital. In each patient, the lesion will be randomly divided into 2 areas A and B, that area A will be treated with 4 sessions of Nd: YAG 1064nm Q-switched laser with intervals of 4 weeks, and area B will be subjected to 4 sessions of treatment with 4 weeks intervals of Er: YAG2940 laser and immediate use of clobetasol ointment.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Clinical signs of amyloidosis; Age range 18-60 years; Existence of at least 1 lesion with an area of 5 to 10 cm²; More than 6 months have passed since the lesion occurred. Exclusion criteria: Pregnancy, Lactation; Decision to become pregnant in the next 5 months; History of hypertrophic scarring; Keloid; Melanoma; Other skin cancers, Treatment with systemic retinoids in the last 6 months; Any systemic treatment (for this disease) during last 3 months; Any topical treatment in the last month.

Intervention groups

In all patients, the lesion will be divided into 2 areas, A and B, where area A will be treated with the Q-switch 1064 laser and area B will be treated with Erbium YAG laser. Also, all patients will be treated topically with a combination of Kligman formulation, including: tretinoin, hydroquinone and clobetasol, on a daily basis at home.

Main outcome variables

1-Change in the intensity of pigmentation 2-Changing in the intensity of itching

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200811048363N1**

Registration date: **2021-03-04, 1399/12/14**

Registration timing: **prospective**

Last update: **2021-03-04, 1399/12/14**

Update count: **0**

Registration date

2021-03-04, 1399/12/14

Registrant information

Name

Maral Yazdanpanah

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3667 1163

Email address

marlyyazdan@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-03-05, 1399/12/15

Expected recruitment end date

2021-08-22, 1400/05/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative study of 1064nm Q-switched ND:YAG laser and Er:YAG2940nm laser in treatment of macular amyloidosis

Public title

Comparative study of 1064nm Q-switched ND:YAG laser and Er:YAG2940nm laser in treatment of macular amyloidosis

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients with macular amyloidosis clinical symptoms
Patients with at least 5 to 10 cm² macular amyloidosis skin lesion on the trunk or limbs
At least 6 months have passed since the onset of skin lesion

Exclusion criteria:

Pregnancy, breastfeeding or deciding to get pregnant in the next 2 months
Personal history of hypertrophic scar or keloid formation
Personal history of melanoma or other skin cancers
History of systemic retinoid therapy during last 6 months
History of any systemic treatment during the last 3 months for macular amyloidosis
History of any topical treatment during the last month for macular amyloidosis

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size

Target sample size: **39**

Randomization (investigator's opinion)

Randomized

Randomization description

Due to the fact that in our study both types of interventions will be performed on one person (split lesion method), randomization only applies to the side of the patient's lesion. Our method for randomization is based on even and odd calendar days, so patients referred on the even days, right side of the lesions will be considered area- A (Q-switched laser 1064nm) and the left side of the lesion will be considered as area- B (Erbium laser 2940). For the patients referred on the odd dates allocation of the intervention area will be the opposite.

Blinding (investigator's opinion)

Single blinded

Blinding description

Due to the fact that the type of laser intervention is high-power lasers, in order to protect the patient, he/she should use lead protective eyewear, during the process, so she/he will be unaware of the laser type; results will

be compared by before and after (intervention) photographs, by a neutral specialist who is unaware of the type and location of various treatments.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary IDs**

empty

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

Iran National Committee for Ethics in Biomedical Research

Street address

No32, Baghe-Negar Ave., Chahar-Bagh-bala St., Isfahan

City

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Province

Isfahan

Postal code

8163675791

Approval date

2019-07-09, 1398/04/18

Ethics committee reference number

IR.MUI.MED.REC.1398.185

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

macular amyloidosis

ICD-10 code

E85.4

ICD-10 code description

Organ-limited amyloidosis

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

Intensity changes of pigmentation

Timepoint

Before the intervention (0) ; 4 weeks after the last session of intervention

Method of measurement

photography with a single camera

2**Description**

Intensity changes of pigmentation

Timepoint

Before the intervention (0) ; 4 weeks after the last session of intervention

Method of measurement

Questionnaire with Visual Analogue Scale

3

Description

Intensity changes of itching

Timepoint

Before the intervention (0) ; 4 weeks after the last session of intervention

Method of measurement

Questionnaire with Visual Analogue Scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In each patient, the lesion will be randomly divided into 2 zones A and B (two squares of equal size). Zone A under 4 treatment sessions with 4-week intervals of Nd: YAG 1064nm Q-switched laser (device: HeliosIII) with fluence parameters 14 J/cm², spot size 3mm, energy 1000j. Also for all patients, Kligman combination (including: 0.05% tretinoin, 5% hydroquinone and 0.05% clobetasol in ethanol-based) will be prescribed for daily use on the lesions at home.

Category

Treatment - Other

2

Description

Intervention group: In each patient, the lesion will be randomly divided into 2 zones A and B (two squares of equal size) and zone B will under 4 treatment sessions with 4 weeks intervals of laser Er: YAG2940 (Lotus II device, Laseroptek) with parameters: spot size 10mm / energy: 1500j and fe: 3Hz and immediately take clobetasol ointment. Also for all patients, Kligman combination (including: 0.05% tretinoin, 5% hydroquinone and 0.05% clobetasol in ethanol-based) will be prescribed for daily use on the lesions at home.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Dermatology Clinic of Al-zahra Hospital

Full name of responsible person

Maral Yazdanpanah

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Shaghayegh Haghjooi Javanmard

Street address

Vice Chancellor for Research and Technology,
Building No. 4, Isfahan University of Medical Sciences
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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

Esfahan 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

Esfahan University of Medical Sciences

Full name of responsible person

Maral Yazdanpanah

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Dermatology

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Position

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

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

Study Protocol

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

Statistical Analysis Plan

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

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

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

Data Dictionary

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