Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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 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

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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 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 considred area- A (Q-switched laser 1064nm) and the left side of the lesion will 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 befor 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 Commitee for Ethnics in Biomedical Research

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

City
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Province
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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 and Health Services, Hezar Jerib St.
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sh_haghjoo@med.mui.ac.ir
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
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Other areas of specialty/work
Dermatology
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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