Clinical Trial Protocol
Iranian Registry of Clinical Trials

27 Jul 2026

Evaluation of the Efficacy, Safety, Satisfaction, Tolerability, and Durability of Q-Switched Nd:YAG 1064 nm Laser in Combination with co2 Laser and Each Laser Alone in the Treatment of Macular Amyloidosis in Patients Undergoing Modified Klignman’s Formula Therapy: A Randomized, Four-Arm, Split-Face, Assessor-Blinded Clinical Trial

Protocol summary

Study aim

To evaluate the efficacy of fractional Q-switched Nd:YAG laser compared to co2 laser and to compare each monotherapy with their combined use in the treatment of macular amyloidosis.

Design

Fifteen patients were enrolled, with affected areas divided into four treatment zones: Fractional QS Nd:YAG co2 Combined lasers Control (topical only) Blinding: Double-blind (patients & assessors unaware of treatment allocation)

Settings and conduct

The combined laser intervention was performed on hyperpigmented lesions at Rasool Akram Medical Center under double-blind conditions, with both participants and evaluators blinded to treatment allocation across study zones.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Female patients aged 18–50 years with a confirmed diagnosis of macular amyloidosis and no history of laser treatment for the condition within the past three months. Exclusion Criteria: Development of hypersensitivity or any treatment-related adverse effects that would prevent continuation of therapy. Pregnancy and Presence of severe underlying systemic diseases

Intervention groups

All enrolled patients will receive topical application of the modified Kligman's formula, to be applied uniformly to all affected and hyperpigmented areas. Following this baseline treatment, the hyperpigmented lesions of each patient will be divided into four distinct zones, with each zone receiving one of the following interventions: Zone 1: Fractional Q-switched Nd:YAG laser treatment Zone 2: co2 laser treatment Zone 3: Combined fractional Q-switched Nd:YAG + co2 laser therapy Zone 4 (Control): Topical Kligman's formula only

Main outcome variables

Resolution of refractory hyperpigmentation. Improvement in patients' quality of life. Identification of optimal treatment for resistant pigmentation disorders

General information

Reason for update

At the time of registering the proposal, based on the facilities available at the center and the malfunction of the center's CO_2 fractional laser device, which made it unusable, the Er:YAG 2940 nm laser was defined as one of the interventional arms in the proposal. During this same sampling period, two patients at the collaborating center underwent treatment with the Er:YAG laser. However, the sampling process was progressing slowly due to travel complications. Considering that after some time the CO_2 device was repaired, and to avoid imposing additional costs, logistical challenges, and therapeutic inconsistencies for the patients, the continuation of the study for the remaining patients was carried out using the CO_2 fractional laser device instead of the Erbium device, with settings adjusted to closely match those of the Erbium device. Since the treatment of two patients with Er:YAG was not consistent with the continuation of the study and could lead to heterogeneity in the data, the results related to these two patients were excluded from the final analysis to preserve the methodological validity of the study. Therefore, it is hereby clarified that the discrepancy between the initially registered title and the final implementation of the study was due to the temporary technical issue with the CO_2 device and the practical necessities in the patient treatment process. This change did not compromise the nature of the study,

the randomization method, the blinding of the evaluators, or the main research protocol, and solely involved replacing the Er:YAG intervention with the CO_2 fractional laser in the respective study arm.

Acronym

IRCT registration information

IRCT registration number: **IRCT20231104059946N1**
Registration date: **2025-05-08, 1404/02/18**
Registration timing: **retrospective**

Last update: **2025-12-09, 1404/09/18**
Update count: **1**

Registration date

2025-05-08, 1404/02/18

Registrant information

Name

paria jafary

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-02-15, 1402/11/26

Expected recruitment end date

2025-02-14, 1403/11/26

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the Efficacy, Safety, Satisfaction, Tolerability, and Durability of Q-Switched Nd:YAG 1064 nm Laser in Combination with co2 Laser and Each Laser Alone in the Treatment of Macular Amyloidosis in Patients Undergoing Modified Klignman’s Formula Therapy: A Randomized, Four-Arm, Split-Face, Assessor-Blinded Clinical Trial

Public title

Combined Laser Modalities for the Treatment of Macular Amyloidosis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Female patients aged 18 to 50 years Confirmed diagnosis of macular amyloidosis No prior laser treatment for the condition within the last three months Absence of significant underlying medical conditions Patient compliance with treatment protocols and ability to attend all therapy sessions Non-pregnant status and no plans for pregnancy within the next six months No active infections No hypersensitivity to retinoids or their derivatives No active rheumatologic diseases (e.g., lupus)

Exclusion criteria:

Development of hypersensitivity or any adverse reaction to the treatment interventions that would preclude continuation of therapy Pregnancy or plans for pregnancy within the next 6 months Active infection Active lupus or other active rheumatologic diseases Hypersensitivity to retinoids or their derivatives Immunodeficiency disorders Patient unwillingness to continue treatment

Age

From **18 years** old to **50 years** old

Gender

Female

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **15**
More than 1 sample in each individual
Number of samples in each individual: **4**
In this study, patients with extensive macular amyloidosis (involving the trunk and extremities) refractory to topical treatments were enrolled. All participants were initially prescribed a topical combination medication with modified Kligman’s formula (hydroquinone 4g + vitamin C 3g + retinol 3cc + in cold cream base up to 100g), to be applied uniformly to all affected areas. Subsequently, hyperpigmented lesions were divided into four distinct zones, each receiving one of the following interventions administered by the study operator: Fractional Q-switched laser (Zone 1), 1),co2 laser (Zone 2), combined fractional Q-switched + co2 lasers (Zone 3), and topical Kligman’s formula alone (Zone 4, control).

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Due to the significant differences between the mentioned therapeutic interventions, blinding of the patient and the treating physician was not feasible. Therefore, the study will be conducted in a single-blind manner. In other words, outcome assessments will be performed by an evaluator blinded to the type of intervention (a dermatologist unaware of which treatment was administered to specific areas of the patient’s skin), based on standardized photographs of the lesions taken at each session. Additionally, data analysis will be conducted by a blinded statistician

Placebo

Not used

Assignment

Factorial

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Iran University of Medical Sciences

Street address

Unit 2, No. 13, Nik Roshfard St., Shadmehr St., Tehran

City

tehran

Province

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Postal code

1456744319

Approval date

2023-10-09, 1402/07/17

Ethics committee reference number

IR.IUMS.FMD.REC.1402.302

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

hyperpigmentation improvement percentage

Timepoint

Assessments were conducted at three timepoints: (1) baseline, (2) pre-second session (3 weeks later), and (3) 4 weeks after the second intervention.

Method of measurement

photography- Doctor's evaluation- Patient's self-assessment

Secondary outcomes

empty

Intervention groups

1

Description

Intervention Group: Fractional Q-Switched Laser Group (Zone 1)

Category

Treatment - Other

2

Description

Intervention Group: co2 Laser Group (Zone 2)

Category

Treatment - Other

3

Description

Intervention Group: Combined Fractional Q-Switched Nd:YAG and co2 Laser Therapy (Zone 3)

Category

Treatment - Other

4

Description

Control Group: Topical Kligman's Formula Therapy

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Fatemeh Hospital - Dermatology Clinic

Full name of responsible person

Paria jafary

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Fateme Hospital,23th street,Yosefabad

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

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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
Iran 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
Iran University of Medical Sciences

Full name of responsible person
Dr. Paria Jafary

Position
resident

Latest degree
Medical doctor

Other areas of specialty/work
Dermatology

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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
Not applicable

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Study data will be made publicly available after analysis and de-identification of participants as part of the outcome publication.

When the data will become available and for how long

Following publication of the clinical trial results in international journals, the research data will become accessible

To whom data/document is available

All researchers at medical science universities are permitted to access the study data.

Under which criteria data/document could be used

All researchers are permitted to use the data or documentation provided that they properly acknowledge the original authors.

From where data/document is obtainable

Researchers may contact Dr. Paria Jafary at the following email address to request related documentation: p.jafary74@gmail.com

What processes are involved for a request to access data/document

All requested documentation will be provided to applicants within a maximum period of one month, subject to compliance with the stated conditions.

Comments