

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Comparative study of efficacy 4 lasers: PDL, QSwitch-Nd-YAG, CO2 and CO2+Qswitch-Nd-YAG in treatment of cutaneous macular amyloidosis

Protocol summary

Study aim

Comparative study of efficacy 4 lasers: PDL, QSwitch-Nd-YAG, CO2 and CO2+Qswitch-Nd-YAG in treatment of cutaneous macular amyloidosis

Design

IV-phase Randomized, parallel group trial with non-blinded outcome in case group

Settings and conduct

To comparative of efficacy 4 lasers on treatment of patients with cutaneous macular amyloidosis referred to Dermatology Clinic of Ahvaz Imam Khomeini Hospital, the ulcer divided to 4 sections and each one treated with one of PDL, QSwitch-Nd-YAG, CO2 and CO2+Qswitch-Nd-YAG lasers.

Participants/Inclusion and exclusion criteria

Inclusion criteria: All patients with cutaneous macular amyloidosis referred to Dermatology Clinic of Ahvaz Imam Khomeini Hospital
Exclusion criteria: history of allergy due to laser therapy

Intervention groups

1st Intervention group: the first quarter of ulcer treated with PDL laser. 2th Intervention group: the second quarter of ulcer treated with QSwitch-Nd-YAG laser. 3th Intervention group: the Third quarter of ulcer treated with CO2 laser. 4th Intervention group: the last quarter of ulcer treated with CO2+Qswitch-Nd-YAG laser.

Main outcome variables

ulcer improvement

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181217042026N1**

Registration date: **2019-01-15, 1397/10/25**

Registration timing: **registered_while_recruiting**

Last update: **2019-01-15, 1397/10/25**

Update count: **0**

Registration date

2019-01-15, 1397/10/25

Registrant information

Name

Forough Ghanatir

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 61 3587 4366

Email address

ghanatir.f@ajums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-09-23, 1397/07/01

Expected recruitment end date

2019-03-16, 1397/12/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative study of efficacy 4 lasers: PDL, QSwitch-Nd-YAG, CO2 and CO2+Qswitch-Nd-YAG in treatment of cutaneous macular amyloidosis

Public title

Comparative study of efficacy 4 lasers: PDL, QSwitch-Nd-YAG, CO2 and CO2+Qswitch-Nd-YAG in treatment of cutaneous macular amyloidosis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

All patients with cutaneous macular amyloidosis referred to Dermatology Clinic of Ahvaz Imam Khomeini Hospital

Exclusion criteria:

history of allergy due to laser therapy

Age

No age limit

Gender

Both

Phase

4

Groups that have been masked

No information

Sample size

Target sample size: **30**

More than 1 sample in each individual

Number of samples in each individual: **4**

one quarter of ulcer

Randomization (investigator's opinion)

N/A

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

Ahvaz Jundishapur University of Medical Sciences

Street address

Ahvaz Jundishapur University of Medical Sciences,
Golestan Boulevard, Ahvaz, Iran

City

Ahvaz

Province

Khouzestan

Postal code

1234567899

Approval date

2018-07-21, 1397/04/30

Ethics committee reference number

IR.AJUMS.REC.1397.376

Health conditions studied

1

Description of health condition studied

cutaneous macular amyloidosis

ICD-10 code

L99.0

ICD-10 code description

Amyloidosis of skin

Primary outcomes

1

Description

ulcer improvement

Timepoint

after laser therapy and 4 months after that

Method of measurement

observation of ulcer area

Secondary outcomes

empty

Intervention groups

1

Description

1st Intervention group: the first quarter of ulcer treated with PDL laser.

Category

Treatment - Other

2

Description

2th Intervention group: the second quarter of ulcer treated with QSwitch-Nd-YAG laser.

Category

Treatment - Other

3

Description

3th Intervention group: the Third quarter of ulcer treated with CO2 laser.

Category

Treatment - Other

4

Description

4th Intervention group: the last quarter of ulcer treated with CO2+Qswitch-Nd-YAG laser.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Ahvaz Imam Khomeini Hospital

Full name of responsible person
Seyed Mohammad Radmanesh
Street address
Ahvaz Imam Khomeini Hospital, Azadegan Ave.,
Ahvaz, Iran
City
Ahvaz
Province
Khouzestan
Postal code
1234567899
Phone
+98 61 3587 4366
Email
radmanesh-m@ajums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Ahvaz University of Medical Sciences
Full name of responsible person
Mohammad Badavi
Street address
Ahvaz Jundishapur University of Medical Sciences,
Golestan Boulevard, Ahvaz, Iran
City
Ahvaz
Province
Khouzestan
Postal code
1234567899
Phone
+98 61 3587 4366
Email
src@ajums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Ahvaz 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
Ahvaz University of Medical Sciences

Full name of responsible person

Forough Ghanatir

Position

Student

Latest degree

Medical doctor

Other areas of specialty/work

Dermatologist

Street address

Ahvaz Jundishapur University of Medical Sciences,
Golestan Boulevard, Ahvaz, Iran

City

Ahvaz

Province

Khouzestan

Postal code

1234567899

Phone

+98 61 3587 4366

Fax

Email

ghanatir.f@ajums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Seyed Mohammad Radmanesh

Position

Professor

Latest degree

Subspecialist

Other areas of specialty/work

Dermatologist

Street address

Ahvaz Jundishapur University of Medical Sciences,
Golestan Boulevard, Ahvaz, Iran

City

Ahvaz

Province

Khouzestan

Postal code

1234567899

Phone

+98 61 3587 4366

Email

radmanesh-m@ajums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Forough Ghanatir

Position

Student

Latest degree

Medical doctor

Other areas of specialty/work

Dermatologist

Street address

Ahvaz Jundishapur University of Medical Sciences,
Golestan Boulevard, Ahvaz, Iran

City

Ahvaz

Province

Khouzestan

Postal code

1234567899

Phone

+98 61 3587 4366

Fax**Email**

ghanatir.f@ajums.ac.ir

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

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

belong to the Ahvaz Jundishapur University of Medical
Sciences opinion

When the data will become available and for how long

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To whom data/document is available

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Under which criteria data/document could be used

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From where data/document is obtainable

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

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Sciences opinion

Comments