

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Jun 2026

Evaluation the effect of Fractional Erbium glass 1540 Laser on treatment of macular amyloidosis

Protocol summary

Study aim

This study aims to evaluate the effect of Fractional Erbium glass 1540 Laser on treatment of macular amyloidosis.

Design

This clinical trial is conducted among female patients with macular amyloidosis in upper back areas. Patients, after being diagnosed with macular amyloidosis by a dermatologist, will be notified about the advantages and disadvantages of this trial and in case of agreement they will be asked to fill out written consent forms to be included in the study. Then, patients' lesions are divided to 2 areas by random. One side is then treated with Fractional Erbium glass 1540 Laser (area A) and the other side, as control group, receives no treatment (area B).

Settings and conduct

No blinding will be done in the study and patients are those referring to Dermatology Clinic of Imam Reza Hospital. The following indices will be separately evaluated. 1-Clinical assessment: during each visit and also 4 and 12 weeks after last visit, digital images are taken from both areas by a Canon camera and are analyzed by computers. Primary evaluation is done by 2 blinded researchers based on factors such as rate and pattern (with or without rippling) of pigmentation, intensity of lesions and itching. The aforementioned factors are then measured 3 months after last visit as final evaluation. 2-Subjective assessment or patient global assessment: patients, same as specialists, are asked to grade their satisfaction during follow ups by numbers 0 to 5 with 0 meaning no improvement and 5 meaning complete satisfaction. 3-Safety assessment: includes recording erythema and edema rate by specialist and rate of pain after each visit based on VAS (visual analogue scale).

Participants/Inclusion and exclusion criteria

Inclusion criteria: Clinically confirmed macular amyloidosis; macular amyloidosis lesions should be on

upper back area; no current skin diseases like active dermatitis, active acne, hypertrophic scars or keloids. Exclusion criteria: intolerance against laser treatment; pregnancy during treatment; other dermatologic diseases like skin infections and active lesions in the treatment area.

Intervention groups

Patients' lesions are divided to 2 areas by random. One side is then treated with Fractional Erbium glass 1540 Laser (area A) and the other side, as control group, receives no treatment (area B).

Main outcome variables

based on rate and pattern of pigmentation, intensity of lesions and itching.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20140414017271N4**

Registration date: **2018-02-04, 1396/11/15**

Registration timing: **registered_while_recruiting**

Last update: **2018-02-04, 1396/11/15**

Update count: **0**

Registration date

2018-02-04, 1396/11/15

Registrant information

Name

Yalda Nahidi

Name of organization / entity

department of dermatology, Ebne Sina St, Emam Reza hospital

Country

Iran (Islamic Republic of)

Phone

+98 51 1802 2490

Email address

nahidiy@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Mashhad University of Medical Sciences

Expected recruitment start date

2016-07-25, 1395/05/04

Expected recruitment end date

2018-02-08, 1396/11/19

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation the effect of Fractional Erbium glass 1540 Laser on treatment of macular amyloidosis

Public title

Evaluation the effect of Laser on treatment of macular amyloidosis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Clinically confirmed macular amyloidosis macular amyloidosis lesions should be on upper back area o current skin diseases like active dermatitis, active acne, hypertrophic scars or keloids patients with Fitzpatrick skin types 2 to 4 written informed consent from patients for participation in the study and digital imaging from lesions no use of Isotretinoin during the last 3 month having no heart pacemaker no record of sensitivity to lidocaine

Exclusion criteria:

unreal expectations from treatment results macular amyloidosis lesions not being on upper back areas intolerance against laser treatment pregnancy during treatment unwillingness of patient to continue participating in the study or digital imaging from lesions Coagulopathy Patients who were under topical treatment one month before study existence of hypertrophic scars or keloids Treatment with systemic retinoid during the last 6 month other dermatologic diseases like skin infections and active lesions in the treatment area

Age

No age limit

Gender

Female

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: 15

Randomization (investigator's opinion)

Randomized

Randomization description

Then, patients' lesions are divided to 2 areas by random. One side is then treated with Fractional Erbium glass 1540 Laser (area A) and the other side, as control group, receives no treatment (area B).

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 Mashhad University of Medical Sciences

Street address

Central Building of Mashhad University of Medical Sciences (Ghorshi), Daneshgah 16, Daneshgah Street

City

Mashhad

Province

Razavi Khorasan

Postal code

9138813944

Approval date

2016-06-08, 1395/03/19

Ethics committee reference number

IR.MUMS.fm.REC.1395.36

Health conditions studied

1

Description of health condition studied

macular amyloidosis

ICD-10 code

L99.0

ICD-10 code description

Amyloidosis of skin

Primary outcomes

1

Description

Lesion pigmentation

Timepoint

During therapy, after each laser session and three month after last session

Method of measurement

Based on a grading system (1:low, 2:medium,

3:noticeable)

2

Description

Rate of rippling

Timepoint

During therapy, after each laser session and three month after last session

Method of measurement

Based on a grading system (0:without rippling, 1:with rippling)

3

Description

Intensity of lesion

Timepoint

During therapy, after each laser session and three month after last session

Method of measurement

Based on a grading system (0:without Lichenification, 1:with Lichenification)

4

Description

Itching

Timepoint

During therapy, after each laser session and three month after last session

Method of measurement

Based on a grading system (0:without itching, 1:with itching)

Secondary outcomes

empty

Intervention groups

1

Description

intervention group: one part of lesion receives Fractional non-ablative erbium laser for 3 sessions and its energy ranges from 8 to 15 Mj/MB2.

Category

Treatment - Other

2

Description

control group: one part of lesion receives no treatment.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Dermatology clinic, Imam Reza Hospital

Full name of responsible person

Dr Rozita Delghandi

Street address

Imam Reza Hospital, Imam Reza square, Ebn_e_sina Avenue

City

Mashhad

Province

Razavi Khorasan

Postal code

9137913316

Phone

+98 51 3802 2020

Email

delghandir931@mums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Dr Mohsen Tafaghodi

Street address

Central Building of Mashhad University of Medical Sciences (Ghorshi), Daneshgah 16, Daneshgah street

City

Mashhad

Province

Razavi Khorasan

Postal code

9138813944

Phone

+98 51 3841 2081

Email

ramresearch@mums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Mashhad 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

Mashhad University of Medical Sciences
Full name of responsible person
Dr. Rozita Delghandi
Position
Assistant of dermatology
Latest degree
Medical doctor
Other areas of specialty/work
Dermatology
Street address
Imam Reza Hospital, Imam Reza square, Ebn_e_sina Avenue
City
Mashhad
Province
Razavi Khorasan
Postal code
9137913316
Phone
+98 51 3802 2020
Fax
Email
delghandir931@mums.ac.ir
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Dr Yalda Nahidi
Position
Associate professor
Latest degree
Specialist
Other areas of specialty/work
Dermatology
Street address
Imam Reza Hospital, Imam Reza square, Ebn_e_sina Avenue
City
Mashhad
Province
Razavi Khorasan
Postal code
9137913316
Phone
+98 51 3802 2020
Fax
Email
nahidiy@mums.ac.ir
Web page address

Person responsible for updating data

Contact
Name of organization / entity

Mashhad University of Medical Sciences
Full name of responsible person
Akram Momenzadeh
Position
Bachelor of Biology
Latest degree
Master
Other areas of specialty/work
Biochemistry
Street address
Ghaem Hospital, Ahmad Abad Avenue
City
Mashhad
Province
Razavi Khorasan
Postal code
9137913316
Phone
+98 38022078
Fax
Email
src@mums.ac.ir
Web page address

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

All data can be shared after patients are made unidentifiable.

When the data will become available and for how long

Data can be accessible 6 months after results are published.

To whom data/document is available

Data will be available for researchers in universities and other scientific institutes.

Under which criteria data/document could be used

Carrying out analysis on data is permitted.

From where data/document is obtainable

Data can be accessible through sending an email to the corresponding author.

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

After sending a request email to the corresponding author, data will be sent in 1 month.

Comments