Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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)

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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 Raza Hospital
Full name of responsible person
Dr Rozita Delghandi
Street address
Imam Reza Hospital, Imam Reza square, Ebn_e_sina Avenue
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Mashhad
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Email
delghandir931@mums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mashhad 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
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
Assisstant of dermatology
Latest degree
Medical doctor
Other areas of specialty/work
Dermatology
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Person responsible for scientific inquiries

Contact
Name of organization / entity
Mashhad University of Medical Sciences
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Dr Yalda Nahidi
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Associate professor
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Person responsible for updating data

Contact
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Full name of responsible person
Akram Momenzadeh
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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
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