Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of the Effectiveness of 308-nm Xenon Chloride Excimer Laser on the Treatment of Patchy Alopecia Areata

Protocol summary

Study aim
Determine the effectiveness of 308-nm Excimer laser therapy in Patients with Alopecia Areata

Design
A randomized Clinical trial with single groups, community-based, investigator-blinded

Settings and conduct
Patients go to Razi Hospital every week and each session undergo an laser beam therapy.Each session the dose of laser therapy increases by 100 mj. Also, in another lesion of patients a determined dose of corticosteroid will be administered monthly

Participants/Inclusion and exclusion criteria
Inclusion criteria: 1.Age 18-60 years 2.alopecia areata with clinical diagnosis by a dermatologist 3.Have at least 2 lesions or more (multi-patchy) in the face or scalp 4.lesion size at least 2 cm in 2 cm 5.In the last 3 months, has not recieved any drug for the hair loss Non-inclusion criteria: 1.Progressive alopecia areata during the clinical trial 2.Having Other types of alopecia such as Totalis or universalis or ophiasis 3.Pregnancy and breastfeeding when entering the study 4.Any other cause of hair loss other than alopecia areata

Intervention groups
Patients' lesions are divided into 2 groups. One group is exposed to the excimer laser and the other group is undergone the influence of corticosteroid therapy

Main outcome variables
Percentage of hair regrowth according to clinical photographs as gross hair regrowth and also according to phototrichogram pictures concerning dermoscopic characteristics of the disease

General information

Reason for update
Upon completion of the study, additional information was entered. The start and end dates of the patient recruitment and study were completed. In the blinding section, the evaluators were unaware of the allocation of study groups and rated the outcomes blindly. The main treatment variable was also written in more detail.

Acronym

IRCT registration information
IRCT registration number: **IRCT20150923024147N1**
Registration date: **2019-02-04, 1397/11/15**
Registration timing: **prospective**

Last update: **2021-05-02, 1400/02/12**
Update count: **1**

Registration date
2019-02-04, 1397/11/15

Registrant information

Name
maryam daneshpajooh

Name of organization / entity
Tehran university of medical scienses

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-04-04, 1398/01/15

Expected recruitment end date
2019-08-06, 1398/05/15

Actual recruitment start date
2019-07-29, 1398/05/07

Actual recruitment end date
2020-02-01, 1398/11/12

Trial completion date
2020-05-25, 1399/03/05

Scientific title
Comparison of the Effectiveness of 308-nm Xenon Chloride Excimer Laser on the Treatment of Patchy Alopecia Areata

Public title
Excimer Laser in Alopecia Areata

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
clinical diagnosis of alopecia areata by a dermatologist Having at least 2 lesions or more (multiple-patchy) in the face or scalp The size of the lesions is at least 2 cm in 2 cm has not used a drug for the lesions, In the last 3 months

Exclusion criteria:
Having alopecia totalis or alopecia universalis or ophiasis Pregnancy breast feeding An underlying disease such as endocrine diseases or immonological disorders causes hair loss If hair loss has a cause other than alopecia areata. Taking a drug (systemically or topical) causes hair loss or hair regrowth in the last 3 months Surgical treatment such as hair transplantation for the treatment of hair loss. Any dermatological diseases such as skin cancer, infection which can cause hair loss Photosensivity If the patient becomes pregnant during the study patients unwillingness to continue cooperation in the clinical trial Progression of disease during the clinical trial

Age
From **18 years** old to **60 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Outcome assessor

Sample size
Target sample size: **35**
More than 1 sample in each individual
Number of samples in each individual: **2**
one lesion is beamed by excimer laser and one lesion is injection with tramcinolone 5mg/ml
Actual sample size reached: **16**
More than 1 sample in each individual
Actual sample size in each individual: **6**
alopecic patches in each person

Randomization (investigator's opinion)
Randomized

Randomization description
One of the lesions that has the inclusion criteria is undergone the beam of excimer radiation by use of permuted block randomization. And one of the other lesions is considered as a control for steroid injection

Blinding (investigator's opinion)
Single blinded

Blinding description
Two dermatologists evaluated the photographs and phototrichograms of three assessments of the baseline, after the last treatment session, and after one month of follow-up blindly.

Placebo
Not used

Assignment
Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Tehran University of Medical Sciences

Street address
No. 1, Poorsina Ave., Ghods Ave., Enghelab Ave.

City
Tehran

Province
Tehran

Postal code
1417653761

Approval date
2019-01-12, 1397/10/22

Ethics committee reference number
IR.TUMS.MEDICINE.REC.1397.689

Health conditions studied

1

Description of health condition studied
Alopecia Areata

ICD-10 code
L63

ICD-10 code description
Alopecia areata

Primary outcomes

1

Description
The percentage of hair regrowth

Timepoint
At at baseline, after the last treatment session (session 12); and after one month of follow-up, the percentage of hair regrowth is measured.

Method of measurement
1.By phototrichogram(fotofinder) device. 2.by Photographic evaluation by 2 other dermatologists 3.By general assessment of the patient

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: another category of the lesions are treated with an excimer laser treatmentThe patient will visit the center for 12 sessions (once a week). In each session, the patient's lesion that was selected based on the initial blockage, is irradiated by the excimer laser beam .The laser start dose is 100 to 200 milijoule, depending on the skin type and increases by as much as 100 milijoule per square centimeter in each volume. In the event of complications such as laser-induced burns, the laser treatment of that session is discontinued and after the necessary steps and treatment with topical steroids in the next session, the dosage would be reduced by 100 mJ in the next session

Category
Treatment - Devices

2

Description
Control group: Patients' lesions are divided into two groups: one treatment group, corticosteroid injections (40 mg/ml triamcinolone acetonide diluted with lidocaine or distilled water) are treated monthly with 5 mg/ml in 3 sessions(once a month) for the patient.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Razi hospital

Full name of responsible person
Maryam Daneshpazhooh

Street address
Razi hospital, Wahdat-e-Islami Ave., Tehran, District 12

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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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
Tehran 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
Tehran University of Medical Sciences

Full name of responsible person
Nika Kianfar

Position
Student

Latest degree
Medical doctor

Other areas of specialty/work
Dermatology

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Person responsible for scientific inquiries

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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 patient information can be shared without naming and identifying them.

When the data will become available and for how long
Details of the data are immediately available after publishing the results.

To whom data/document is available
All researchers and health professionals working in academic, scientific and medical institutions.

Under which criteria data/document could be used
The data is only shared for person whose purpose is to improve the therapeutic course of alopecia areata. Any The type of statistical analysis can be done in order to improve the treatment.

From where data/document is obtainable
Tehran University of Medical Sciences professor Maryam Daneshpazhooh Dermatologist Razi hospital, Wahdat-e-Islami Ave., Tehran, District 12 Phone number: +98 912 130 6662 Email: maryamdanesh.pj@gmail.com

What processes are involved for a request to access data/document
Information is available immediately after verifying that the applicant's circumstances are met by the competent authorities.

Comments