

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 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 received 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 daneshpajooch

##### Name of organization / entity

Tehran university of medical sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 5561 8989

##### Email address

daneshpj@tums.ac.ir

##### 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 immunological 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 Photosensitivity 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 treatment. The 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

##### City

Tehran

##### Province

Tehran

##### Postal code

1199663911

##### Phone

+98 21 5560 9951

##### Email

razihospital@sina.tums.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Tehran University of Medical Sciences

#### Full name of responsible person

Maryam Daneshpazhooh

#### Street address

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

#### City

Tehran

#### Province

Tehran

#### Postal code

tel:1199663911

#### Phone

+98 21 5561 8989

#### Email

maryamdanesh.pj@gmail.com

#### 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

##### Street address

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

##### City

Tehran

##### Province

Tehran

##### Postal code

1199663911

##### Phone

+98 21 5561 8989

##### Email

Nika\_kianfar@yahoo.com

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Maryam Daneshpazhooh

**Position**

Professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Dermatology

**Street address**

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

**City**

Tehran

**Province**

Tehran

**Postal code**

1199663911

**Phone**

+98 21 5560 9951

**Email**

maryamdanesh.pj@gmail.com

## Person responsible for updating data

### 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

**Street address**

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**Phone**

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**Email**

Nika\_kianfar@yahoo.com

## 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**