

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Comparative study of the effectiveness of fractional CO2 laser with topical triamcinolone acetonide versus intralesional triamcinolone acetonide injection in the treatment of patients with alopecia areata

#### Protocol summary

##### Study aim

Comparative study of the effectiveness of fractional CO2 laser with topical triamcinolone acetonide versus intralesional triamcinolone acetonide injection in the treatment of patients with alopecia areata referred to Razi Hospital

##### Design

A randomized, single-blind, parallel-group, controlled clinical trial was conducted based on randomized blocks on 35 patients with alopecia areata.

##### Settings and conduct

Razi Hospital, Allopath Patch Patients are randomly divided into two groups A and B: Group A: Treated with CO2 laser plus topical triamcinolone acetonide cream Group B: Treated with intradermal triamcinolone acetonide injection Both groups received 4 sessions of treatment at 4-week intervals. Treatment efficacy was assessed by SALT score, dermoscopy, and VAS/VDS scales. Alopecia areata predictive score was measured according to dermoscopic criteria. Adverse events collected from both treatments were assessed by a dermatologist who was blinded to the treatment method performed on each patch (evaluator). Also, side effects and patient satisfaction are recorded.

##### Participants/Inclusion and exclusion criteria

Patients with alopecia areata (AA) over 15 years of age who have at least 2 or more comparable, anatomically similar, symmetrical alopecia patches on both sides of the head, at least 2 cm apart, and SALT less than 25%, and who have not received systemic medication or intralesional injection effective for alopecia areata in the last 2 months, will be included in the study. Also, patients with systemic diseases, immunocompromised patients, and pregnant patients were excluded from the study.

##### Intervention groups

Treatment (A, i.e. laser + topical triamcinolone) and treatment (B, i.e. local injection of triamcinolone with a

needle) are used randomly in the right or left alloplic patch for each patient.

##### Main outcome variables

Increase Severity of Alopecia Tool score

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20251003067487N1**

Registration date: **2025-10-12, 1404/07/20**

Registration timing: **registered\_while\_recruiting**

Last update: **2025-10-12, 1404/07/20**

Update count: **0**

##### Registration date

2025-10-12, 1404/07/20

##### Registrant information

##### Name

Bahar Sadeghi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 5288 8282

##### Email address

baharsadeghi045@gmail.com

##### Recruitment status

**recruiting**

##### Funding source

##### Expected recruitment start date

2025-10-12, 1404/07/20

##### Expected recruitment end date

2026-10-12, 1405/07/20

##### Actual recruitment start date

empty  
**Actual recruitment end date**  
empty  
**Trial completion date**  
empty

**Scientific title**  
Comparative study of the effectiveness of fractional CO2 laser with topical triamcinolone acetonide versus intralesional triamcinolone acetonide injection in the treatment of patients with alopecia areata

**Public title**  
Studying the effect of fractional CO2 laser in the treatment of alopecia areata

**Purpose**  
Treatment

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
Patients with alopecia areata over 15 years of age Have at least 2 or more comparable, anatomically similar, symmetrical alopathic patches on both sides of the head at least 2 cm apart. Alopecia severity scoring system is less than 25%. They have not received systemic medication or intralesional injection effective for alopecia areata in the last 2 months.

**Exclusion criteria:**  
Immunocompromised patients Pregnant patients Patients with systemic diseases - cardiac, renal and hepatic disorders

**Age**  
From **15 years** old

**Gender**  
Both

**Phase**  
2-3

**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**  
The right or left patch of alopecia areata will receive the indicated treatments based on randomization.

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
The study method is a clinical trial, patients receive the desired treatment using the randomization method in the form of a random list, which is explained below. For this purpose, we assign an English letter to each of the treatment methods, which in this study, since two types of treatment are examined, treatment (A, i.e. co2 laser) and treatment (B, i.e. local injection of triamcinolone with a needle) are used. Treatment (A, i.e. microneedle) and treatment (B, i.e. local injection of triamcinolone with a needle) are used. On the other hand, since each patient receives both treatments and statistical methods have more power with equal volume in each treatment group, in order to obtain equal sample size for each treatment method, we proceed as follows: we define two drug

combinations AB and BA. The AB combination means that treatment A will be injected for the person's right side and treatment B for the person's left side. Similarly, the BA combination means that treatment B will be injected for the person's right side and treatment A for the person's left side. Next, to prepare the random list, a random number table is used in such a way that a random number from 0 to 9 is generated for each patient. If the generated number is between 0 and 4, the AB combination is considered, and if the selected number is between 5 and 9, the BA combination is considered. To prepare the random list, the Random Allocation Software will be used, the output of which is reported below.

**Blinding (investigator's opinion)**  
Single blinded

**Blinding description**  
The randomized, parallel-group clinical trial was designed as a single-blind study. Thus, each alopecia patch was assigned to only one of the two intervention or control groups. In order to maintain blinding, the interventions in the two groups were made similar in terms of appearance, method of administration, and visit schedule. Randomization codes were generated by an independent researcher and stored in sealed envelopes. The outcome assessor was also unaware of the allocation of patients to treatment groups, and the grouping codes were only revealed after data collection was completed and the database was locked. This blinding method minimized the possibility of bias in the assessment of intervention effectiveness.

**Placebo**  
Not used

**Assignment**  
Parallel

**Other design features**

**Secondary Ids**

empty

**Ethics committees**

1

**Ethics committee**  
**Name of ethics committee**  
Research Ethics Committee, Tehran University of Medical Sciences  
**Street address**  
6th Floor, Room 604, Central Building, Tehran University of Medical Sciences, Qods Street Intersection, Keshavarz Boulevard  
**City**  
Tehran  
**Province**  
Tehran  
**Postal code**  
1199663911

**Approval date**  
2025-07-07, 1404/04/16

**Ethics committee reference number**

## 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

Severity of Alopecia Tool (SALT) Score

#### Timepoint

Before the intervention begins - at each session - one month after the end of treatment

#### Method of measurement

As observed by a dermatologist and scored according to the relevant system/Scoring is based on clinical and dermoscopy photographs.

### 2

#### Description

Pain

#### Timepoint

After each treatment session

#### Method of measurement

Visual discomfort scale (VDS)

### 3

#### Description

Patient satisfaction with hair growth

#### Timepoint

After each treatment session

#### Method of measurement

Visual analogue scale (VAS)

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Control group: Alopecia patches are mapped on a transparent sheet and a graph paper to calculate the area of each patch in square centimeters. In the control patch, intralesional injection treatment of triamcinolone at the same dose (10 mg/mL) is used at a dose of 0.1 mL/cm<sup>2</sup>.

#### Category

Treatment - Drugs

### 2

#### Description

Intervention group: Intervention group: Topical anesthetic cream Xyla P (lidocaine + prilocaine) was applied to the site 45 minutes before the laser and after achieving satisfactory local anesthesia, the treated area was cleaned with a gauze soaked in distilled water. The eyes were protected with a shield and the CO<sub>2</sub> laser was used with the following settings:As a pilot, with a density of 120-144/energy of 10, 2 minutes after laser treatment, topical triamcinolone acetonide solution is applied to the site, based on the measured area of the lesion, at a rate of 0.05 cc per square centimeter. Patients in this group receive the aforementioned treatment in 4 sessions at 4-week intervals.

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Razi Hospital

##### Full name of responsible person

Narges ghandi

##### Street address

Razi Dermatology Hospital, Vahdat-e Eslami Street

##### City

Tehran

##### Province

Tehran

##### Postal code

119963911

##### Phone

+98 21 5561 8989

##### Email

Nghandi@tums.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Tehran University of Medical Sciences

##### Full name of responsible person

Ramin Kordi

##### Street address

Tehran University of Medical Sciences, 16th Azar Street, Keshavarz Boulevard

##### City

Tehran

##### Province

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##### Postal code

119963911

##### Phone

+98 21 8898 9487

##### Email

Nghandi@tums.ac.ir

**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**

Narges ghandi

**Position**

Professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Dermatology

**Street address**

Razi Dermatology Hospital, Vahdate Eslami street

**City**

Tehran

**Province**

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**Postal code**

1199663911

**Phone**

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**Email**

Nghandi@tums.ac.ir

## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Narges ghandi

**Position**

Professor

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Specialist

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## Person responsible for updating data

**Contact**

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Narges ghandi

**Position**

Professor

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**Phone**

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**Email**

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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**

after making the data unidentifiable, it would be publishable.

**When the data will become available and for how long**

3 months after publishing the article

**To whom data/document is available**

It will be available to researchers working in academic and scientific institutions.

**Under which criteria data/document could be used**

those who send emails to the corresponding author.

**From where data/document is obtainable**

To receive the documentation of this research, please submit your request to the email address of Dr. Narges Ghandi (corresponding author) at Nghandi@tums.ac.ir.

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

Send an email to the author responsible for the study, documents, and data within two weeks to a maximum of one month from the date of submitting the request. The data will be sent in Excel format and, if requested, clinical photographs of the patients.

**Comments**