

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 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)

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+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/cm².

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 CO2 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

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119963911

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Email

Nghandi@tums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

Ramin Kordi

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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

Narges ghandi

Position

Professor

Latest degree

Specialist

Other areas of specialty/work

Dermatology

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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

Latest degree

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Other areas of specialty/work

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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

Latest degree

Specialist

Other areas of specialty/work

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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