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 allopic 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

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Iran (Islamic Republic of)

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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 allopathic 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

IR.TUMS.MEDICINE.REC.1404.244

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

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Tehran

Province

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Postal code

۱۱۹۹۶۶۳۹۱۱

Phone

+98 21 5561 8989

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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

Specialist

Other areas of specialty/work

Dermatology

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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

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Email

Nghandi@tums.ac.ir

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