Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

A single-blind clinical trial pilot study of the efficacy and safety of microneedle skin patch carrying triamcinolone in the treatment of alopecia areata compared to local injection of triamcinolone with a needle

Protocol summary

Study aim

Evaluation of the efficacy and safety of a microneedle skin patch containing triamcinolone in reducing the volume of alopecia areata and comparing its efficacy with conventional needle injections in patients diagnosed with alopecia areata referred to Razi Skin Hospital.

Design

A randomized, single-blind, parallel-group, controlled clinical trial was conducted based on randomized blocks on 10 patients with alopecia areata.

Settings and conduct

At Razi Hospital, at the end of the patient collection, the patient's photos are reviewed and scored for hair growth by a dermatologist who is unaware of the treatment method performed on each patch (the evaluator). The evaluator does not know what treatment each patient received. Patients with AA over 18 years of age with a clinical diagnosis and meeting the inclusion criteria for AA limited to the scalp. Treatment (A, i.e. microneedle) and treatment (B, i.e. local injection of triamcinolone with a needle) are used randomly in the right or left allotopic patch for each patient.

Participants/Inclusion and exclusion criteria

Alopecia areata(AA) patients over 18 years of age with independent clinical diagnosis by a dermatologist and meeting the AA entry criteria of limited scalp AA of less than 20% limited to the scalp and at least two patches that do not require systemic treatment are selected.Patients who had previously been treated for AA within the past 12 weeks or had any autoimmune or systemic disease were excluded from the study.

Intervention groups

Treatment (A, i.e. microneedle) and treatment (B, i.e. local injection of triamcinolone with a needle) are used randomly in the right or left allotopic 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: **IRCT20250228064873N3**
Registration date: **2025-10-04, 1404/07/12**
Registration timing: **prospective**

Last update: **2025-10-04, 1404/07/12**
Update count: **0**

Registration date

2025-10-04, 1404/07/12

Registrant information

Name

Ifa Etesami

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 5561 8989

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-10-23, 1404/08/01

Expected recruitment end date

2026-10-23, 1405/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
A single-blind clinical trial pilot study of the efficacy and safety of microneedle skin patch carrying triamcinolone in the treatment of alopecia areata compared to local injection of triamcinolone with a needle

Public title
evaluation of efficacy and safety of microneedle skin patch carrying triamcinolone in the treatment of alopecia areata compared to local injection of triamcinolone with a needle

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Alopecia areata patient over 18 years of age with independent clinical diagnosis by a dermatologist At least two patches that do not require systemic treatment Alopecia areata limited to the scalp SALT SCORe less than 20% limited to the scalp
Exclusion criteria:
Patients who have previously been treated for alopecia areata within the past 12 weeks Have any autoimmune or systemic disease

Age
From **18 years** old

Gender
Both

Phase
2

Groups that have been masked
- Data analyser

Sample size
Target sample size: **10**

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. microneedle) 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, Tehran, Iran
City
tehran
Province
Tehran
Postal code
1199663911

Approval date
2025-03-25, 1404/01/05

Ethics committee reference number
IR.TUMS.MEDICINE.REC.1404.024

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

Individuals are followed up monthly for up to three months. Before the intervention begins, 1-2-3 months after the intervention.

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 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: Alopecia patches are mapped on a transparent sheet and a graph paper to calculate the area of each patch in square centimeters.In this group, patients undergo microneedling with topical triamcinolone injection. The total calculated dose is divided into two equal parts to be used before and after microneedling. After application, the patient is asked not to wash the treated area for the next few hours.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Razi Hospital

Full name of responsible person

Ifa Etesami

Street address

Razi Dermatology Hospital, Vahdat-e Eslami Street

City

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Province

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Postal code

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Email

Ifa.etesami@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

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
Ifa Etesami

Position
Associate professor

Latest degree
Specialist

Other areas of specialty/work
Dermatology

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Full name of responsible person
Ifa Etesami

Position
Associate professor

Latest degree
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Person responsible for updating data

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Position
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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
academic researchers and industrial workers.

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. Ifa Etesami (responsible author) at ifa.etesami@gmail.com.

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