Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jun 2026

comparison of the effect of combined intralesional Triamcinolone with topical Bimatoprost versus intralesional Triamcinolone or topical Bimatoprost in the treatment of alopecia areata

Protocol summary

Study aim

Determination and comparison of the improvement of alopecia areata lesion site based on PGA score, SALT score, and dermoscopic findings in the three studied groups, controlling for the possible effect of age, gender, and lesion site.

Design

3 parallel-group, single-blind, randomized, phase 3 clinical trial on 42 patients. A sealed envelope site was used for randomization.

Settings and conduct

This study includes 48 patients with alopecia areata referred to the clinic of Imam Khomeini Hospital. Evaluation of lesions by dermoscopy and photography will be performed before the start of treatment and one month after the last stage of treatment. It is single-blind, meaning that the physician evaluating the results will be unaware of the treatment method used.

Participants/Inclusion and exclusion criteria

Patients over 18 years of age who have at least one patch of alopecia areata and have not received treatment in the last three months and do not have any contraindications to treatment such as pregnancy, breastfeeding, and local allergy or infection.

Intervention groups

The first group will be treated with intralesional triamcinolone injection (5mg/ml for scalp alopecia and 2.5mg/ml for facial alopecia), the second group will be treated with bimatoprost 0.01% every 12 hours, and the third group will be treated with a combination of monthly triamcinolone injection and topical bimatoprost.

Main outcome variables

Age; Gender; Lesion site improvement based on Physician Assessment System (PGA) score; Patient satisfaction; Dermoscopy findings; SALT scoring

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20251014067632N1**
Registration date: **2026-04-28, 1405/02/08**
Registration timing: **registered_while_recruiting**

Last update: **2026-04-28, 1405/02/08**
Update count: **0**

Registration date

2026-04-28, 1405/02/08

Registrant information

Name

Negin Soozangar

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 61 3292 1837

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negin.sgr@gmail.com

Recruitment status

recruiting

Funding source

Expected recruitment start date

2026-02-03, 1404/11/14

Expected recruitment end date

2026-07-05, 1405/04/14

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
comparison of the effect of combined intralesional Triamcinolone with topical Bimatoprost versus intralesional Triamcinolone or topical Bimatoprost in the treatment of alopecia areata

Public title
effect of bimatoprost on alopecia areata

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
 People over 18 years of age with the hair loss pattern of alopecia areata who have at least one or more patches of alopecia. Consent to participate in the study.

Exclusion criteria:
 Sensitivity to the medications used. Pregnancy and breastfeeding. Systemic treatment has been performed within the past 3 months or topical treatment has been performed within the past 2 weeks. The site of application of the medicine is infected. Patients with pattern universalis or ophiasis or totalis Patients with spontaneous hair regrowth in the area of hair loss Patients with other dermatological diseases simultaneously

Age
From **18 years** old

Gender
Both

Phase
3

Groups that have been masked

- Outcome assessor

Sample size
Target sample size: **42**

Randomization (investigator's opinion)
Randomized

Randomization description
Using the randomization method, patients are divided into three groups. A sealed envelope site is used to divide patients, and randomization is performed in blocks, and each block consists of 6 patients and includes 2 groups A, 2 groups B, and 2 groups C. In order to eliminate the effect of the interpretation of the researcher and the performing physician, in addition to observing blinding, the technique of concealing the allocation of numbers and letters was used, and the names of the groups were hidden.

Blinding (investigator's opinion)
Single blinded

Blinding description
The physician evaluating the results will be unaware of the treatment method used. At the beginning of treatment and one month after the last session, photographs of the lesions will be taken using a Xiaomi Redmi note11 pro mobile phone at a distance of 30 cm.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Ahvaz Jundishapur University of Medical Sciences

Street address
No.2004, Unit 10, 5th Floor, Asadi8 Complex, 48 Daneshjoo St., daneshgah Town

City
ahwaz

Province
Khouzestan

Postal code
6134933357

Approval date
2024-10-28, 1403/08/07

Ethics committee reference number
IR.AJUMS.REC.1404.303

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
amount of change in the SALT score (from 0 to 100).

Timepoint
At the beginning of treatment and one month after the end of treatment

Method of measurement
According to the areas involved in the scalp /left side:18% , right side=18%)/ ,top=40%,back=24 / (S0=no hair loss/ s1=<25% hair loss/ s2= 25%-49% hair loss/ s3=50%-74% hair loss/ s4=75-99%hairloss/ s5=100% total scalp hair loss)

2

Description
Changes in dermoscopy findings

Timepoint
At the beginning of treatment and one month after the end of treatment

Method of measurement
Based on the researcher's observation (determining the number of black dots, yellow dots, broken hairs, exclamation mark hairs, villous hairs)

3

Description
Checking the rate of change in GPA score
Timepoint
At the beginning of treatment and one month after the end of treatment
Method of measurement
Evaluation of patient outcomes by a physician outside the study based on the response rate to treatment using photographs taken before and one month after treatment (from 0 to 4) (A0 = no improvement / A1 = poor response <25% / A2 = good response 25 to 50% / A3 = very good response 50 to 75% / A4 = excellent response 75 to 100%)

Secondary outcomes

empty

Intervention groups

1

Description
Control group: was treated with intralesional triamcinolone injection (5mg/ml for scalp alopecia and 2.5mg/ml for facial alopecia) monthly for three months.
Category
Treatment - Drugs

2

Description
Intervention group:Under treatment with bimatoprost 0.01% every 12 hours for three months
Category
Treatment - Drugs

3

Description
Intervention group: Under combination treatment of monthly triamcinolone injections and topical bimatoprost every 12 hours for three months
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Khomeini hospital
Full name of responsible person
Tara Barat
Street address
Imam Khomeini hospital, azadegan st.
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6193673166
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negin.sgr@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Ahvaz University of Medical Sciences
Full name of responsible person
dr.abdollah rafeai
Street address
Ahvaz Jundishapur University, North Esfand Street, Golestan Alley
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itc@ajums.ac.ir
Web page address
https://vchresearch.ajums.ac.ir/
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Ahvaz 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
Ahvaz University of Medical Sciences
Full name of responsible person
Negin Soozangar

Position
Dermatology Assistant
Latest degree
Medical doctor
Other areas of specialty/work
Dermatology
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Person responsible for updating data

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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
Research data, including anonymized consent forms and before-and-after photos of patients' results, along with basic information including gender and age, will be shared.
When the data will become available and for how long
Access begins 6 months after publication of the article.
To whom data/document is available
Only for researchers working in academic and scientific institutions
Under which criteria data/document could be used
To conduct further studies in this field or other parallel and related studies.
From where data/document is obtainable
To receive the documents, please send a request to Dr. Negin Sozengar's email: negin.sgr@gmail.com. If there is no response, please send a request to the address: Dermatology Department Office, 3rd Floor, Imam Hospital, Azadegan Street, Ahvaz, Khuzestan.
What processes are involved for a request to access data/document
After registering the request in writing, along with the phone number and details of the applicant, to the email or address mentioned, a response will be received within one week after the necessary checks. The reason for requesting the documents should also be mentioned.
Comments