

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 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)

Phone

+98 61 3292 1837

Email address

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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Email

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

Street address

Unit 10, 5th floor, asadi8 complex, No.2009,
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Person responsible for scientific inquiries

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Ahvaz University of Medical Sciences

Full name of responsible person

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Person responsible for updating data

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Full name of responsible person

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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 Soozangar'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