

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

Comparison of efficacy, side effects, and patient satisfaction in patients with limited scalp areata alopecia in a multiple group study with Latanoprost, Minoxidil, and Betamethasone

Protocol summary

Study aim

Finding a cost-benefit , effective, painless, safe and satisfactory treatment for limited alopecia areata

Design

This is a phase 3 clinical trial, randomized, controlled and blinded study , which will be performed on 108 patients. Patients will be classified randomly into 6 parallel groups (5 treatment groups and 1 control group). For randomization, the "permuted block randomization" method will be used.

Settings and conduct

Patients will be selected from Rasoul Akram Hospital dermatology clinic and the follow-up visits would be done in weeks 2 and 6.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1)Patients with localized areata alopecia of beard or scalp (<3 patches), 2) Not receiving any medication for areata alopecia for at least 1 month before the beginning of the study, 3) Signing an informed written consent. Exclusion criteria: 1) Patients with extensive alopecia (> 3 patches). 2) Patients with any systemic disorder, ophthalmic pathology, other dermatological diseases, skin atrophy, or infection at the alopecic region. 3) Patients with allergy or hypersensitivity to any component of the treatment products. 4) Pregnant and lactating women

Intervention groups

Group 1: eyedrop Latanoprost 0.005% Group 2: solution Minoxidil 5% Group 3: eyedrop Latanoprost 0.005% and solution Minoxidil 5% Group 4: solution Betamethasone 0.1% and solution Minoxidil 5% Group 5: solution Betamethasone 0.1% and eyedrop Latanoprost 0.005% Group 6 (control) : solution Betamethasone 0.1%

Main outcome variables

1) The severity of alopecia, before and after therapy, will be measured by the Severity of Alopecia Tool (SALT) score. 2)Patients' satisfaction with treatment.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20211109053013N1**

Registration date: **2021-12-03, 1400/09/12**

Registration timing: **prospective**

Last update: **2021-12-03, 1400/09/12**

Update count: **0**

Registration date

2021-12-03, 1400/09/12

Registrant information

Name

Nafise Yazdanian

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 6643 6277

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-12-06, 1400/09/15

Expected recruitment end date

2022-02-19, 1400/11/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of efficacy, side effects, and patient satisfaction in patients with limited scalp areata alopecia in a multiple group study with Latanoprost, Minoxidil, and Betamethasone

Public title

Comparison of efficacy, side effects, and patient satisfaction in patients with limited scalp areata alopecia in a multiple group study with Latanoprost, Minoxidil, and Betamethasone

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with localized areata alopecia of beard or scalp (<3 patches) Not receiving any medication for areata alopecia for at least 1 month before the beginning of the study Signing an informed written consent

Exclusion criteria:

Patients with extensive alopecia (> 3 patches) Patients with any systemic disorder , ophthalmic pathology, other dermatological diseases, skin atrophy, or infection at the alopecic region Patients with allergy or hypersensitivity to any component of the treatment products Pregnant and lactating women

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Data analyser

Sample size

Target sample size: **108**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, 108 patients will be divided equally into 5 intervention groups and one control group. For randomization, the "permuted block randomization" method will be used. In this method, the randomization unit will be a block. Different scenarios of intervention groups and control groups will be designed in 18 blocks of 6. The blocks will be numbered and placed inside a container. Then the blocks would be randomly selected and the patients will be treated based on the scenario of the selected block.

Blinding (investigator's opinion)

Double blinded

Blinding description

Data will be held to a dermatologist , without being informed of the patients' treatment , for assessments and analysis .

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Iran University of Medical Sciences

Street address

No.30, East 24th Ave, Azadegan Blvd, Amirabad district

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Province

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Postal code

1437683662

Approval date

2020-08-15, 1399/05/25

Ethics committee reference number

IR.IUMS.FMD.REC.1399.338

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

The severity of alopecia was determined by the severity of alopecia tool (SALT) score before and after therapy. Scalp hair loss grading will be as below: S0=no hair loss; S1 < 25% hair loss; S2 =25-49%hair loss; S3=50-74% hair loss; S4=75-99% hair loss and S5=100% hair loss. Grades of body hair loss included: B0, nobody hair loss; B1, some body hair loss, and B2, 100% body(excluding scalp) hair loss.

Timepoint

Calculation of SALT score at the beginning of the study (before the intervention) and 2 and 6 weeks after treatment begins.

Method of measurement

Regrowth was calculated as [(SALT score at base line-SALTscore at follow-up)/SALT score at base line] × 100 and was categorized as A0= no change or further loss, A1=1-24% regrowth, A2=25-49% regrowth, A3=50-74% regrowth, A4=75-99%regrowth and A5=100% regrowth.

Secondary outcomes

1

Description

Patients' satisfaction of treatment

Timepoint

At the beginning of the study (before the intervention) and 2 and 6 weeks after treatment begins.

Method of measurement

By using a questionnaire: (1= no response, 2=fair improvement,3=good improvement, 4=very good improvement and 5=excellent improvement)

Intervention groups

1

Description

Intervention group: Latanoprost 0.005% topical eye drops alone; Apply 50 microliters (1 drop) twice daily.

Category

Treatment - Drugs

2

Description

Intervention group: topical minoxidil solution 5% alone; 1 cc twice daily

Category

Treatment - Drugs

3

Description

Intervention group: topical eye drops Latanoprost 0.005% and topical solution minoxidil 5%; Latanoprost 50 µl (1 drop) in the morning and Minoxidil 1 cc in the afternoon

Category

Treatment - Drugs

4

Description

Intervention group: Topical betamethasone solution 0.1 and topical minoxidil solution 5%: betamethasone 1 cc in the morning and minoxidil 1 cc in the evening

Category

Treatment - Drugs

5

Description

Intervention group: Topical betamethasone solution 0.1 and latanoprost eye drops 0.005%: betamethasone 1 cc in the morning and latanoprost 50 µl (1 drop) in the evening

Category

Treatment - Drugs

6

Description

Control group: Topical betamethasone 0.1 solution, 1 cc twice daily

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Rasool e akram Hospital

Full name of responsible person

Nafise Yazdanian

Street address

Hazrate Rasoole Akram Hospital, Niayesh St, Satarkhan Ave, Tehran town

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Iran University of Medical Sciences

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Iran University of Medical Sciences ,Shahid Hemmat Highway, Tehran

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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

Iran 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**

Iran University of Medical Sciences

Full name of responsible person

Nafise Yazdanian

Position

resident

Latest degree

Medical doctor

Other areas of specialty/work

Dermatology

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Other areas of specialty/work

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Person responsible for updating data**Contact****Name of organization / entity**

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Position

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no more information

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available