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)

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+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

City
Tehran

Province
Tehran

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
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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
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Phone
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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
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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