Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Evaluation of clinical efficacy of latanoprost drop 0.005% for the treatment of patients with scalp patchy alopecia

Protocol summary

Study aim

Evaluation of clinical efficacy of latanoprost drop 0.005% for the treatment of patients with scalp patchy alopecia

Design

This study was a double-blind randomized clinical trial with a control group that was performed in phase 3 of the trial. Thirty patients were divided into two groups using simple randomization method (taking out numbers from 01 to 30 from the sealed envelope). The randomization process was performed by the secretary (who was independent of the original researchers). Randomization was performed before a patient entered the study and the intervention was assigned according to his group therapy.

Settings and conduct

This study was conducted on patients with patchy alopecia who were referred to the dermatology clinic of Bu-Ali Sina Hospital in Sari. Patients were randomly assigned to two groups.The first and second groups received latanoprost drops 0.005% or placebo, respectively. The drug and placebo packaging was completely identical, and the patient, evaluator, and information analyzer were unaware for the patient group.

Participants/Inclusion and exclusion criteria

Patients over 12 years old who suffering from patchy alopecia were included in the study. Exclusion criteria were include liver and kidney diseases, diabetes, autoimmune diseases, and the use of immunosuppressive drugs.

Intervention groups

Intervention group: Patients who received topical corticosteroids (clobetasol in isopropyl alcohol) with 0.005% latanoprost drops twice a day. Control group: Patients who received topical corticosteroids with latanoprost placebo twice daily.

Main outcome variables

The area of scalp with hair loss at the beginning of the study, the end of the first, second and third months was compared with the photo.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20090813002342N11**
Registration date: **2020-10-07, 1399/07/16**
Registration timing: **retrospective**

Last update: **2020-10-07, 1399/07/16**
Update count: **0**

Registration date

2020-10-07, 1399/07/16

Registrant information

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Mohammad Reza Rafati
Name of organization / entity
Mazandaran University of Medical Sciences
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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-06-11, 1397/03/21

Expected recruitment end date

2019-03-19, 1397/12/28

Actual recruitment start date

2018-06-11, 1397/03/21

Actual recruitment end date

2019-05-20, 1398/02/30

Trial completion date

2019-05-20, 1398/02/30

Scientific title
Evaluation of clinical efficacy of latanoprost drop 0.005% for the treatment of patients with scalp patchy alopecia

Public title
The effect of latanoprost for the treatment of patient with scalp patchy alopecia

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Patient with scalp patchy alopecia Minimum age 12 years
Exclusion criteria:
Pregnancy Liver disease Kidney disease Diabetes Autoimmune diseases Use of immunosuppressive drugs

Age
From **12 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **30**
Actual sample size reached: **24**

Randomization (investigator's opinion)
Randomized

Randomization description
Using a simple randomization method, individuals who met the inclusion criteria and completed the informed consent form were assigned to two groups. The procedure was as follows: beads numbered 01 to 30 were placed in a sealed envelope. When a patient met the inclusion criteria and the exclusion criteria, a number was took out from the envelope by lottery. If the number was odd, the patient was assigned to group 1 and if it was even, the patient was assigned to group 2. The randomization process was performed by the department secretary (who was independent of the principal investigators). Randomization was performed when a patient entered the study and the intervention was assigned according to his group therapy. For allocation concealment the envelope containing the numbers was closed again and opened only to enter the next patient to draw lottery.

Blinding (investigator's opinion)
Double blinded

Blinding description
The patient knew he might be in the intervention or placebo group but did not know which group he was in. The clinical evaluator and the person responsible for the statistical analysis were not aware of the patient group. All patients in the case and control groups received topical corticosteroids (clobetasol in isopropyl alcohol) twice daily, but patients in the case group also received 0.005% latanoprost drop (twice daily) and patients in the control group received placebo (twice a day). Both the drug and the placebo were prepared by the Sinadarou factory, Iran. So that the appearance of the drug dosage form and its content, apart from its active ingredient, were exactly the same. Clobetasol cream was prepared from Daroupakhsh factory, Iran.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Mazandaran University of Medical Sciences
Street address
College of Pharmacy, Payambar Azam Complex, 18 Km Farah Abad Blvd.
City
Sari
Province
Mazandaran
Postal code
4847193698

Approval date
2017-08-13, 1396/05/22

Ethics committee reference number
IR.MAZUMS.REC.1396.3137

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
Hair loss area

Timepoint
At the beginning of the study, the end of the first, second and third months

Method of measurement
Hair loss site photo

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Patients in this group received latanoprost drop 0.005% at a rate of 5 drops per 3 cm2 baldness (twice daily) with clobetasol in isopropyl alcohol (twice daily). Latanoprost drop 0.005% and clobetasol cream were prepared from Sinadarou factory (Iran) and Daroupakhsh factory (Iran) respectively.
Category
Treatment - Drugs

2

Description
Control group: Patients in this group received a placebo drop of latanoprost at the rate of 5 drops per 3 cm2 of baldness (twice a day) with clobetasol in isopropyl alcohol (twice a day). Latanoprost drop placebo and clobetasol cream were prepared from Sinadarou factory (Iran) and Daroupakhsh factory (Iran) respectively.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Bu-Ali Sina hospital
Full name of responsible person
Masoud Golpur
Street address
Dermatology Clinic, Bu-Ali Sina hospital, Pasdaran St.
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
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4815733971
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Email
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Web page address
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Mazandaran 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
Mazandaran University of Medical Sciences
Full name of responsible person
Mohammad Reza Rafati
Position
Associate Professor of Clinical Pharmacy
Latest degree
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Other areas of specialty/work
Medical Pharmacy
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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
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
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
All data is shareable after unidentified individuals.
When the data will become available and for how long
Access period starts 6 months after the results are published
To whom data/document is available
Researchers in academic and scientific institutions
Under which criteria data/document could be used
For information on the details of the study without doing new statistical analysis
From where data/document is obtainable
Sending an email to mrrafati@mazums.ac.ir
What processes are involved for a request to access data/document
The email will be checked if the request is clear and the information conditions are met Information is sent.
Comments