

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jul 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

Name

Mohammad Reza Rafati

Name of organization / entity

Mazandaran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 15 1354 3083

Email address

mrrafati@mazums.ac.ir

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 taken 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.

City

Sari

Province

Mazandaran

Postal code

4815838477

Phone

+98 11 3334 7837

Email

golpour1334@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Majid Saedi

Street address

Moalem Square

City

Sari

Province

Mazandaran

Postal code

4815733971

Phone

+98 11 3325 7230

Email

pajoheshi@mazums.ac.ir

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

Ph.D.

Other areas of specialty/work

Medical Pharmacy

Street address

Faculty of Pharmacy, Payambar Azam Complex, 18 Km Farah Abad Blvd.

City

Sari

Province

Mazandaran

Postal code

4847193698

Phone

+98 11 3354 3084

Email

mrrafati@mazums.ac.ir

Person responsible for scientific 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

Ph.D.

Other areas of specialty/work

Medical Pharmacy

Street address

Faculty of Pharmacy, Payambar Azam Complex, 18
Km Farah Abad Blvd.

City

Sari

Province

Mazandaran

Postal code

4847193698

Phone

+98 11 3354 3084

Email

mrrafati@mazums.ac.ir

Province

Mazandaran

Postal code

4847193698

Phone

+98 11 3354 3084

Email

mrrafati@mazums.ac.ir

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**Person responsible for updating data****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

Ph.D.

Other areas of specialty/work

Medical Pharmacy

Street address

Faculty of Pharmacy, Payambar Azam Complex, 18
Km Farah Abad Blvd.

City

Sari