

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Jul 2026

Comparison of the therapeutic effects of 5% Minoxidil solution alone with 5% Minoxidil solution and 0.005% Latanoprost in men with androgenetic alopecia

Protocol summary

Study aim

Determining and comparing the therapeutic effects of minoxidil solution alone with the combined solution of minoxidil and latanoprost in patients with androgenetic alopecia

Design

Clinical trial, with parallel, double-blind, randomized groups

Settings and conduct

50 patients referred to the dermatology clinic of Al-Zahra Hospital in Isfahan, after confirming the conditions for admission to the study and fully explaining the process and purpose of the study, and completing informed moral consent, are individually and randomly divided into two groups. this is a double-blinded study and the participants and the evaluator are unaware of the type of drug used for each person. Subjects are randomly divided into two treatment groups: Minoxidil 5%, Latanoprost 0.005% and Minoxidil 5%.

Participants/Inclusion and exclusion criteria

Inclusion criteria: The diagnosis of androgenic alopecia based on Hamilton diagnostic criteria, the severity of hair loss 2 to 5 according to Hamilton criteria and stages 1 and 2 according to Ludwig scale and patient satisfaction to participate in the study. Exclusion criteria: having a history or observation of allergies to any of the Minoxidil and Latanoprost drugs, having a history of heart disease and taking blood pressure medications, other types of alopecia such as alopecia areata, any systemic skin disease

Intervention groups

In this study, patients in one group consumed 1.5 cc of minoxidil solution, each solution equivalent to 20 drops twice a day, and in the other group, consumed a combination of latanoprost 0.005% and minoxidil 5% in the same way for 6 months.

Main outcome variables

Hair density; Severity of hair loss

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20211228053553N1**

Registration date: **2022-01-09, 1400/10/19**

Registration timing: **registered_while_recruiting**

Last update: **2022-01-09, 1400/10/19**

Update count: **0**

Registration date

2022-01-09, 1400/10/19

Registrant information

Name

Amirhossein Bagherkamareh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2613 8376

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-12-30, 1400/10/09

Expected recruitment end date

2022-02-09, 1400/11/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the therapeutic effects of 5% Minoxidil solution alone with 5% Minoxidil solution and 0.005% Latanoprost in men with androgenetic alopecia

Public title

Evaluation of the effect of Latanoprost in the treatment of androgenetic alopecia

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Satisfaction of the patient and his family to participate in the study Confirmation of androgenetic alopecia by two experienced dermatologists based on Hamilton diagnostic criteria Age 18 to 45 years 2 to 5 hair loss severity according to Hamilton criteria The duration of hair loss is less than 10 years

Exclusion criteria:

History or observation of allergies to any of the drugs Minoxidil and Latanoprost, history of heart disease and use of antihypertensive drugs Receiving systemic treatment for androgenic alopecia during the 6 months before the study of other types of alopecia such as alopecia areata, telogen effluvium, anagen effluvium scarring alopecia, any systemic skin disease

Age

From **18 years** old to **45 years** old

Gender

Male

Phase

3

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

50 eligible patients were selected and after studying the informed consent form; in a simple and individual random method with the help of random allocation software, each patient was assigned a number and divided into two groups by random allocation.

Blinding (investigator's opinion)

Double blinded

Blinding description

The two solutions of minoxidil and the combined solution of latanoprost and minoxidil are already prepared by the pharmacist in the same volume and with the same color and shape, and are marked with codes A and B and will be given to the patients. Therefore, the patient and the researcher will not have any information about the two prescription solutions.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Isfahan University of Medical Sciences

Street address

Azadi Square, Hezar Jerib Street

City

isfahan

Province

Isfahan

Postal code

8174673461

Approval date

2021-02-24, 1399/12/06

Ethics committee reference number

IR.MUI.MED.REC.1399.1078

Health conditions studied**1****Description of health condition studied**

Androgenic alopecia

ICD-10 code

L64.9

ICD-10 code description

Androgenic alopecia, unspecified

Primary outcomes**1****Description**

Severity of hair loss

Timepoint

Before and after the intervention

Method of measurement

By a skilled physician based on Hamilton-Norwood for male pattern hair loss

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: Patients in the first intervention group consume 1.5 cc of minoxidil solution, each solution

equivalent to 20 drops twice a day for 6 months.

Category

Treatment - Drugs

2

Description

Intervention group: Patients in the second intervention group consume a combination of latanoprost 0.005% and minoxidil 5% for 6 months.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Alzahra hospital

Full name of responsible person

Nazila poostiyan

Street address

Soffe Boulevard, Isfahan

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Shaghayegh Hagh Jooi Javanmard

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

No

Title of funding source

Isfahan 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

Esfahan University of Medical Sciences

Full name of responsible person

Nazila poostiyan

Position

Associate Professor

Latest degree

Specialist

Other areas of specialty/work

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Person responsible for updating data

Contact

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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