

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Comparative efficacy study of topical finasteride and topical minoxidil versus topical minoxidil alone in male patients with androgenic alopecia.

Protocol summary

Study aim

Comparative efficacy of topical finasteride and topical minoxidil versus topical minoxidil alone in androgenic alopecia in men referring to educational center of Isfahan University of medical sciences

Design

Clinical trial with control group, with a parallel group, double blind, randomized, phase 3 on 40 patients. Random number table was used for randomization.

Settings and conduct

Determining the severity of hair loss by an independent and skilled physician based on the Hamilton and Norwood scale. Counting patients' non-volus hair at the level of 1 cm² in a specific area of the scalp (Hair polarizer)(KC Technology). Standardized global photography. Counting the hairs at the end of week 12 and comparing with the number of hairs at the beginning of the study. Evaluation of the patient for hair regrowth at the end of week 12 according to a 7-point scale. Physician evaluation of hair regrowth at the end of week 12 by comparing pre- and post-treatment photographs according to a 7-point scale. The evaluating physician is not aware of the type of treatment performed.

Participants/Inclusion and exclusion criteria

Men with moderate to severe androgenic alopecia

Intervention groups

The control group received 5% topical minoxidil alone. The experimental group received a topical combination of finasteride 1% and minoxidil 5%.

Main outcome variables

Hair count and hair thickness. Standard photographic score reported by the physician. Patient satisfaction score

General information

Reason for update

Acronym

AGA

IRCT registration information

IRCT registration number: **IRCT20191203045592N2**

Registration date: **2021-02-10, 1399/11/22**

Registration timing: **prospective**

Last update: **2021-02-10, 1399/11/22**

Update count: **0**

Registration date

2021-02-10, 1399/11/22

Registrant information

Name

Samin Nabavinejad

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3131 7715

Email address

saminstrs@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-02-19, 1399/12/01

Expected recruitment end date

2021-03-05, 1399/12/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative efficacy study of topical finasteride and topical minoxidil versus topical minoxidil alone in male patients with androgenic alopecia.

Public title

Comparative efficacy study of topical finasteride in androgenic alopecia

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Men 18-40 years old with moderate to severe androgenic alopecia. Patients should not be treated with oral finasteride or other anti-androgen therapy for the past 6 months. Willingness to participate in the study and fill out the informed consent form. Their diagnosis has been clinically proven and other causes of hair loss have been ruled out.

Exclusion criteria:

Patients with other types of alopecia such as alopecia areata or telogen effluvium. Any serious systemic disease Receiving systemic treatment for androgenic alopecia during the last 6 months.

Age

From **18 years** old to **40 years** old

Gender

Male

Phase

3

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

random number table

Blinding (investigator's opinion)

Double blinded

Blinding description

The evaluating physician and patient are not informed about the type of treatment performed on the patient.

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

Medical school, Isfahan University of Medical sciences, Hezar Jerib St. Isfahan

City

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Province

Isfahan

Postal code

8174673461

Approval date

2021-01-11, 1399/10/22

Ethics committee reference number

IR.MUI.MED.REC.1399.909

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

androgenic alopecia

ICD-10 code

L64

ICD-10 code description

Androgenic alopecia

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

Hair count

Timepoint

At the start of study and 12 weeks later

Method of measurement

Scalp & Hair Polarizing HMS System (KC Technology Company; Korea)

2**Description**

Hair thickness

Timepoint

At the start of study and 12 weeks later

Method of measurement

Scalp & Hair Polarizing HMS System (KC Technology Company; Korea)

3**Description**

Patient's satisfaction score

Timepoint

at the end of 12th week

Method of measurement

The standardized 7 point rating scale (-3 = greatly decreased, -2 = moderately decreased, -1 = slightly decreased, 0 = no change, +1 = slightly increased, +2 = moderately increased, +3 = greatly increased)

4**Description**

physician's assessment based on changes in standard photographs

Timepoint

at the end of 12th week

Method of measurement

The standardized 7 point rating scale (-3 = greatly decreased, -2 = moderately decreased, -1 = slightly decreased, 0 = no change, +1 = slightly increased, +2 = moderately increased, +3 = greatly increased)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Is treated with topical solution of Minoxidil 5% + Finasteride 1% 1 cc twice daily for 12 weeks.

Category

Treatment - Drugs

2

Description

Control group: Use 1 CC of topical 5% minoxidil lotion (Pakdarou co., Tehran, Iran) applied twice daily for 12 weeks.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Al-Zahra University Hospital

Full name of responsible person

Gita Faghihi

Street address

Al-Zahra University Hospital, Soffeh Blvd., Isfahan

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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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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Esfahan 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

Gita Faghihi

Position

Professor of Dermatology

Latest degree

Specialist

Other areas of specialty/work

Dermatology

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Samin Nabavinejad

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Dermatology

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Person responsible for updating data

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Samin Nabavinejad

Position

Resident

Latest degree

Medical doctor