Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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
Isfahan
Province
Isfehan
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

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Esfahan University of Medical Sciences

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Position
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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