

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Efficacy of low dose oral minoxidil Versus topical minoxidil solution for the treatment of androgenetic alopecia.

Protocol summary

Study aim

To compare efficacy of low dose oral minoxidil Versus topical minoxidil solution for the treatment of androgenetic alopecia.

Design

Community based, parallel group, double blind, randomized controlled trial.

Settings and conduct

In this study 80 patients with moderate to severe androgenetic alopecia are enrolled after explaining thoroughly the course and purpose of the study. Patients are randomly assigned to two groups one receiving oral minoxidil tablet and the other receiving 5% topical minoxidil solution. After 6 months of treatment patients are compared and evaluated by standard photography and patient's satisfaction score obtained at the beginning and end of treatment.

Participants/Inclusion and exclusion criteria

Inclusion criteria: clinical diagnosis of AGA; age range between 18-55; patients who haven't received topical or systemic treatment for AGA within 3 months prior to the study. Exclusion criteria: those with other causes of hair loss such as inflammatory or scarring alopecia; any other types of alopecia.

Intervention groups

Intervention group: on oral minoxidil tablet initial starting dose of 2.5 mg per day then gradually increasing the dose to maximum 5 mg per day for 6 months Control group on topical minoxidil solution 5% once daily for six months.

Main outcome variables

Hair thickness; number of hairs; change in photographic pictures and patient's satisfaction score.

General information

Reason for update

Acronym

AGA Androgenetic alopecia

IRCT registration information

IRCT registration number: **IRCT20210823052264N7**

Registration date: **2024-08-16, 1403/05/26**

Registration timing: **registered_while_recruiting**

Last update: **2024-08-16, 1403/05/26**

Update count: **0**

Registration date

2024-08-16, 1403/05/26

Registrant information

Name

Najia Ahmed

Name of organization / entity

PNS shifa

Country

Pakistan

Phone

+92 81 2864092

Email address

najiaomer@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-06-01, 1403/03/12

Expected recruitment end date

2024-11-01, 1403/08/11

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Efficacy of low dose oral minoxidil Versus topical minoxidil solution for the treatment of androgenetic alopecia.

Public title
Efficacy of low dose oral minoxidil Versus topical minoxidil solution for the treatment of androgenetic alopecia.

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Clinical diagnosis of AGA score 2-5 on Norwood-Hamilton classification. Age between 18-55 years. Patients who haven't received topical or systemic treatment for AGA within 3 months prior to the study.
Exclusion criteria:
Those with other causes of hair loss Such as inflammatory or scarring alopecia.any other types of alopecia History of severe systemic diseases (renal, cardiovascular and hepatic) History of some hormonal disorders. History of hypertension,hypotension or on any antihypertensive therapy Hypersensitivity to minoxidil.

Age
From **18 years** old to **55 years** old

Gender
Male

Phase
3

Groups that have been masked

- Participant
- Data analyser

Sample size
Target sample size: **80**

Randomization (investigator's opinion)
Randomized

Randomization description
Simple randomization by lottery method (using sealed envelopes)

Blinding (investigator's opinion)
Double blinded

Blinding description
Double blinded study (participant and data analyser are blinded)

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Institutional ethical review board (IERB) certificate - CMH Quetta
Street address
CMH Quetta

City
Quetta
Postal code
08762
Approval date
2024-05-23, 1403/03/03
Ethics committee reference number
CMH QTA-IERB/18/2024

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
Total hair density,hair thickness and total number of vellus and terminal hairs.
Timepoint
Before start of study and after 1,2,3,6 Months after start of study
Method of measurement
Photographic pictures

2

Description
Patient's satisfaction score
Timepoint
Before study and after 6 months
Method of measurement
Interviewing with the patients

Secondary outcomes

1

Description
Any side effects after taking minoxidil orally or topically
Timepoint
3 monthly
Method of measurement
Interviewing with the patients and clinical examination

Intervention groups

1

Description
Intervention group: on oral minoxidil tablet initial starting dose of 2.5 mg per day then gradually increasing the dose to maximum 5 mg per day for 6 months

Category

Treatment - Drugs

2**Description**

Control group: on topical minoxidil solution 5% once daily for six months.

Category

Treatment - Drugs

Recruitment centers1**Recruitment center****Name of recruitment center**

Combined Military Hospital Quetta

Full name of responsible person

Moniba saeed sheikh

Street address

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Email

saeedmoniba@gmail.com

Sponsors / Funding sources1**Sponsor****Name of organization / entity**

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Fax**Email**

saeedmoniba@gmail.com

Web page address**Grant name**

CMH Quetta

Grant code / Reference number**Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Combined Military Hospital Quetta

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**

Combined Military Hospital

Full name of responsible person

Moniba Saeed Sheikh

Position

Registrar

Latest degree

Subspecialist

Other areas of specialty/work

Dermatology

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Person responsible for updating data

Contact

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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