Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 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 envelops)
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 centers

1

Recruitment center
Name of recruitment center
Combined Military Hospital Quetta
Full name of responsible person
Moniba saeed sheikh
Street address
CMH Quetta
City
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Postal code
08762
Phone
+92 81 9202970
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saeedmoniba@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Combined Military Hospital Quetta
Full name of responsible person
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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 updating data

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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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