Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Comparison of Efficacy of Topical Procapil 5% Versus Topical Minoxidil 5% in Androgenetic Alopecia

Protocol summary

Study aim
This study aims to compare the efficacy of topical Procapil 5% versus topical Minoxidil 5% in the treatment of androgenetic alopecia.

Design
Community based, parallel group, single blinded, RCT

Settings and conduct
In this study 38 patient with moderate to severe AGA are enrolled after explaining thoroughly the course and purpose of study. Patients are randomly assigned one of the two groups, one receiving topical Procapil 5% and the other receiving topical Minoxidil 5% solution twice daily for 6 months.

Participants/Inclusion and exclusion criteria
Inclusion criteria A. Clinical diagnosis of AGA B. Age range of 18 - 55 years, C. Patients who haven't received topical or systemic treatments for AGA within 3 months prior to the study. D. Patient who gave consent for the study Exclusion criteria A. Those with other causes of hair loss such as fungal infection such as taenia capitis, inflammatory or scarring alopecia, hyper-androgenism or other hormonal disorders B. Hypersensitive to the medications C. A history of severe systemic disease (renal, cardiovascular hepatic and lungs). D. Pregnant or breastfeeding patients

Intervention groups
Intervention group 1: Patients in the first group will be treated with Topical Procapil 5% (1 cc twice daily). Intervention group 2: Patients in the second group will receive topical Minoxidil 5% (1 cc twice daily) for 6 months.

Main outcome variables
Number of hairs, Change in photographic pictures and patient satisfaction score.

General information

Reason for update

Acronym
AGA Androgenetic Alopecia

IRCT registration information
IRCT registration number: **IRCT20210823052264N10**
Registration date: **2024-09-26, 1403/07/05**
Registration timing: **registered_while_recruiting**

Last update: **2024-09-26, 1403/07/05**
Update count: **0**

Registration date
2024-09-26, 1403/07/05

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
2024-07-01, 1403/04/11

Expected recruitment end date
2024-12-31, 1403/10/11

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of Efficacy of Topical Procapil 5% Versus Topical Minoxidil 5% in Androgenetic Alopecia

Public title
Comparison of Efficacy of Topical Procapil 5% Versus Topical Minoxidil 5% in Androgenetic Alopecia
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Clinical diagnosis of AGA score 2-5 on Norwood-Hamilton Classification Age range of 18 - 55 years Patients who haven’t received topical or systemic treatments for AGA within 3 months prior to the study. Patient who gave consent for the study
Exclusion criteria:
Those with other causes of hair loss such as fungal infection such as taenia capitis, inflammatory or scarring alopecia, hyper-androgenism or other hormonal disorders Hypersensitive to the medications A history of severe systemic disease (renal, cardiovascular hepatic and lungs) Pregnant or breastfeeding patients
Age
From **18 years** old to **55 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Data analyser

Sample size
Target sample size: **38**
Randomization (investigator's opinion)
Randomized
Randomization description
Simple randomization with Lottery method (using sealed envelops)
Blinding (investigator's opinion)
Double blinded
Blinding description
Double blinded study (participants and data analyzer 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
2024-08-30, 1403/06/09
Ethics committee reference number
CMH QTA-IERB/34/2024

Health conditions studied

1

Description of health condition studied
Androgenetic Alopecia
ICD-10 code
L64.9
ICD-10 code description
Androgenic alopecia, unspecified

Primary outcomes

1

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

2

Description
Patient satisfaction score
Timepoint
After 6 months
Method of measurement
Questionnaire

Secondary outcomes

1

Description
Any side effect after applying minoxidil or Procapil topically
Timepoint
1,2,3 and 6 months
Method of measurement
interviewing the patients and clinical examination

Intervention groups

1

Description
Intervention group: Participants will be given Topical Procapil 5% solution twice daily for 6 months

Category
Treatment - Drugs

2

Description
Control group: Participants will be given Topical Minoxidil 5% solution twice daily for 6 months
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Combined Military Hospital Quetta
Full name of responsible person
Nosheen Abbas
Street address
CMH Quetta
City
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Postal code
08762
Phone
+92 335 0250058
Email
nausheenabbas1122@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Combined Military Hospital Quetta
Full name of responsible person
Nosheen Abbas
Street address
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City
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Postal code
08762
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Email
nausheenabbas1122@gmail.com
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 Quetta
Full name of responsible person
Nosheen Abbas
Position
Registrar
Latest degree
Subspecialist
Other areas of specialty/work
Dermatology
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Person responsible for scientific inquiries

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Person responsible for updating data

Contact

Name of organization / entity
Combined Military Hospital Quetta

Full name of responsible person
Nosheen Abbas

Position
Registrar

Latest degree
Subspecialist

Other areas of specialty/work
Dermatology

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Email
nausheenabbas1122@gmail.com

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