

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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 envelopes)

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

Combined Military Hospital Quetta

Full name of responsible person

Nosheen Abbas

Street address

CMH Quetta

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08762

Phone

+92 335 0250058

Email

nausheenabbas1122@gmail.com

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

Combined Military Hospital Quetta

Full name of responsible person

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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**Contact****Name of organization / entity**

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Person responsible for updating data

Contact

Name of organization / entity

Combined Military Hospital Quetta

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Position

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Latest degree

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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