

# 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 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 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**

Quetta

**Postal code**

08762

**Phone**

+92 81 9202970

**Email**

saeedmoniba@gmail.com

**Sponsors / Funding sources**1**Sponsor****Name of organization / entity**

Combined Military Hospital Quetta

**Full name of responsible person**

Moniba Saeed Sheikh

**Street address**

CMH Quetta

**City**

Quetta

**Postal code**

08762

**Phone**

+92 81 9202970

**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

**Street address**

CMH Quetta

**City**

Quetta

**Province**

Balochistan

**Postal code**

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**Phone**

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**Email**

saeedmoniba@gmail.com

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

Combined Military Hospital Quetta

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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

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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