

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Jun 2026

Determining and comparing the effectiveness of topical Nano-minoxidil and minoxidil on treatment of patients with androgenetic alopecia aged between 18-50 years

Protocol summary

Study aim

Determining and comparing the effectiveness of topical Nano-minoxidil and minoxidil on treatment of patient with androgenetic alopecia

Design

Randomized clinical trial with control and parallel groups, double blind, performed on 84 patients. In this study, permutation block method was used to generate a sequence of random allocation of individuals to the study groups.

Settings and conduct

This study will be conducted on 84 patients with androgenetic alopecia referring to Imam Reza Hospital in Mashhad. After filling out the informed consent form, the patients will be divided into intervention and control groups using block randomization. Patients in the intervention group will be treated with Nano-minoxidil and patients in the control group with minoxidil on a daily basis for 6 months. In this double-blind study, both patients and outcome assessors will be unaware of how patients were assigned to control and intervention groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients are between 18 and 50 with androgenetic alopecia (Sinclair stage 2-5); Exclusion criteria: hypertension, skin lesions such as psoriasis or blister on the scalp, severe Seborrheic dermatitis, history of allergic reaction to minoxidil

Intervention groups

Patients in the intervention group are treated with 1 cc of topical 0.5% Nano-minoxidil and patients in the control group with 1 cc of topical 5% minoxidil daily for 6 months.

Main outcome variables

Hair density and diameter

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20101130005280N62**

Registration date: **2023-06-13, 1402/03/23**

Registration timing: **prospective**

Last update: **2023-06-13, 1402/03/23**

Update count: **0**

Registration date

2023-06-13, 1402/03/23

Registrant information

Name

Raheleh Nejati

Name of organization / entity

Mashhad University of Medical Sciences, Ibn-e- Sina Psychiatric Hospital

Country

Iran (Islamic Republic of)

Phone

+98 51 3711 2540

Email address

nejatir2@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-06-15, 1402/03/25

Expected recruitment end date

2024-02-12, 1402/11/23

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Determining and comparing the effectiveness of topical Nano-minoxidil and minoxidil on treatment of patients with androgenetic alopecia aged between 18-50 years

Public title

Effectiveness of topical Nano-minoxidil and minoxidil on treatment of patients with androgenetic alopecia

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients are between 18 and 50 years of age Patients with androgenetic alopecia (Sinclair stage 2-5)

Exclusion criteria:

Hypertension Skin lesions such as psoriasis or blister on the scalp Severe Seborrheic dermatitis History of allergic reaction to minoxidil

Age

From **18 years** old to **50 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **84**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, permutation block method was used to generate a sequence of random allocation of individuals to the study groups. Random allocation sequence was performed using random allocation software and block size of four. The permutation block method is one of the random allocation methods in which each block is selected according to the number of groups studied.

Blinding (investigator's opinion)

Double blinded

Blinding description

Participants and outcome assessors are fully aware of the subject of the subject, purpose, and procedure of the study. However, in order to prevent prediction of results and introduction of error into the study, they are unaware of the type of grouping and how patients are assigned to control and intervention groups.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Mashhad University of Medical Sciences

Street address

Central Building of Mashhad University of Medical Sciences (Ghorshi), Daneshgah 16, Daneshgah street

City

Mashhad

Province

Razavi Khorasan

Postal code

9138813944

Approval date

2022-11-14, 1401/08/23

Ethics committee reference number

IR.MUMS.IRH.REC.1401.022

Health conditions studied

1

Description of health condition studied

Androgenetic alopecia

ICD-10 code

L64

ICD-10 code description

Androgenic alopecia

Primary outcomes

1

Description

Hair density

Timepoint

Every 2 months for 6 months

Method of measurement

Trichoscopy

2

Description

Hair diameter

Timepoint

Every 2 months for 6 months

Method of measurement

Trichoscopy

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In this group, patients are treated with 1 cc of 0.5% Nano-minoxidil (produced by Dr. Ali Moradi and Dr. Majid Daroudi in the nanobiotechnology department of the medical school of Mashhad university of Medical Sciences) locally on the scalp on a daily basis for 6 months.

Category

Treatment - Drugs

2

Description

Control group: In this group, patients are treated with 1 cc of 5% minoxidil locally on the scalp on a daily basis for 6 months.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza Hospital

Full name of responsible person

Rozhan Farhadi

Street address

Imam Reza Hospital, next to Imam Reza square, Ibne Sina street

City

Mashhad

Province

Razavi Khorasan

Postal code

9137913316

Phone

+98 915 491 4794

Email

rozhanf45@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Dr. Majid Ghayour

Street address

Central Building of Mashhad University of Medical Sciences (Ghorshi), Daneshgah 16, Daneshgah street

City

Mashhad

Province

Razavi Khorasan

Postal code

9177899191

Phone

+98 51 3841 2081

Email

ramresearch@mums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Mashhad University of Medical Sciences

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

Mashhad University of Medical Sciences

Full name of responsible person

Shatila Torabi

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Dermatology

Street address

Imam Reza Hospital, next to Imam Reza square, Ibne Sina street

City

Mashhad

Province

Razavi Khorasan

Postal code

9137913316

Phone

+98 51 3802 2406

Email

TorabiSh@mums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Shatila Torabi

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

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+98 51 3802 2406

Email

TorabiSh@mums.ac.ir

Person responsible for updating data

Contact

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All data can be shared after patients are made unidentifiable.

When the data will become available and for how long

Data can be accessible 6 months after results are published.

To whom data/document is available

Data can be accessible through an email to the corresponding author.

Under which criteria data/document could be used

Data will be available for researchers in universities and other scientific institutes.

From where data/document is obtainable

The data can be accessed through sending an email to Dr. Rozhan Farhadi via rozhanf45@gmail.com.

What processes are involved for a request to access data/document

After sending a request email to the researcher responsible for data collection, Dr. Rozhan Farhadi, at rozhanf45@gmail.com, the data will be provided within 1 month.

Comments