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 Seborrhoeic 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 Scinces, 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 Seborrhoeic 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

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9137913316

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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

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9177899191

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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

Assisstant professor

Latest degree

Specialist

Other areas of specialty/work

Dermatology

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

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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

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Person responsible for updating data

Contact

Name of organization / entity
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Full name of responsible person
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Email
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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