

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Efficacy and safety of minoxidil 5% with or without spironolactone 2% in treating patients with androgenic alopecia

Protocol summary

Study aim

Assessing efficacy of minoxidil 5% versus minoxidil 5%+topical spironolactone 2%

Design

Two arm parallel group randomized trial with blinded outcome assessment phase 2 on 60patients. Block randomization would be used for sampling.

Settings and conduct

Androgenic alopecia patients referred to Razi Hospital in 1401-1402 who are approved based on the inclusion and non-inclusion criteria would be included in this clinical trial. After obtaining written consent from the patient and recording the history, clinical information would be collected in pre-prepared questionnaires. Two groups and each group include 30 patients will be selected. Patients should avoid using other drugs to cure alopecia during the study period. All solutions are kept in a similar bottle where the usage and storage conditions of the medicine are written. The name of the medicine is not written on the bottle. All patients should apply the solution twice a day (morning and night). This procedure continues for 6 months. The patient will visit the medical center for 3 sessions (0-8-16weeks).

Participants/Inclusion and exclusion criteria

Inclusion: Aged 18-60 diagnosis of androgenic alopecia not received any drug for alopecia in the past 12 months
Non-inclusion: Pregnancy or breastfeeding history of internal diseases alteration in diet and lifestyle polycystic ovary syndrome The disease caused by another reason than androgenic alopecia Consuming any systemic or topical drugs caused hair loss or regrowth history of hair transplantation History of skin diseases which cause hair loss like cutaneous cancers, infection, psoriasis photosensitivity

Intervention groups

1st group: minoxidil 5% solution 2nd group: spironolactone 2% solution plus minoxidil 5%

Main outcome variables

Safety and efficacy of the treatments

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181005041243N2**

Registration date: **2022-10-12, 1401/07/20**

Registration timing: **prospective**

Last update: **2022-10-12, 1401/07/20**

Update count: **0**

Registration date

2022-10-12, 1401/07/20

Registrant information

Name

Nika Kianfar

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2285 7201

Email address

N-kianfar@alumnus.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-11-22, 1401/09/01

Expected recruitment end date

2023-05-22, 1402/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Efficacy and safety of minoxidil 5% with or without spironolactone 2% in treating patients with androgenic alopecia		Placebo	Not used
Public title		Assignment	Parallel
Effect of spironolactone and minoxidil solution in treatment of androgenic alopecia		Other design features	
Purpose		Secondary Ids	
Treatment		empty	
Inclusion/Exclusion criteria		Ethics committees	
Inclusion criteria:		1	
Aged 18-60 Clinical diagnosis of androgenic alopecia with a dermatologist Have not received any drug for alopecia in the past 12 months		Ethics committee	
Exclusion criteria:		Name of ethics committee	
Pregnancy or breastfeeding during the intervention history of internal diseases, including endocrine diseases causing alopecia alteration in diet and lifestyle during the study polycystic ovary syndrome The disease caused by another reason than androgenic alopecia Consuming any systemic or topical drugs which caused hair loss or hair regrowth Have a history of hair transplantation History of skin diseases which cause hair loss like cutaneous cancers, infection, psoriasis photosensitivity		Ethics committee of Tehran University of Medical Sciences	
Age		Street address	
From 18 years old to 60 years old		Vahdate eslami St. - Razi alley. Razi Dermatology Hospital	
Gender		City	
Both		Tehran	
Phase		Province	
2-3		Tehran	
Groups that have been masked		Postal code	
• Participant • Care provider • Investigator • Outcome assessor • Data analyser		119963911	
Sample size		Approval date	
Target sample size: 60		2022-10-01, 1401/07/09	
Randomization (investigator's opinion)		Ethics committee reference number	
Randomized		IR.TUMS.MEDICINE.REC.1401.509	
Randomization description		Health conditions studied	
Individual blocks will be created without stratified randomization by statistical software (Website of SealedEnvelope TM). And another person (rather than the doctor-researcher-patient) would do the randomization. For this, blocks of size 6 were selected for 2 treatment groups so that the total sample size would be 60. Based on this, a randomized sequence will be provided according to which the study subjects will receive the treatment.		1	
Blinding (investigator's opinion)		Description of health condition studied	
Double blinded		Androgenic alopecia	
Blinding description		ICD-10 code	
The container containing the medicines will be without a drug name label and all the containers will be similar and indistinguishable. Another person out of the study will distribute the desired medicine to the patients based on the randomization sequence. Therefore, the physician, the outcome assessor, and the analyzer will remain unaware of the drug's content. According to the mentioned points, this study will be double-blind.		L64	
		ICD-10 code description	
		Androgenic alopecia	
		Primary outcomes	
		1	
		Description	
		Hair regrowth score	
		Timepoint	
		At the beginning of the study (before the start of the intervention) and 6 months after the start of trial	
		Method of measurement	
		Hair regrowth score based on the observations of two dermatologists assessing the before and after photographs	
		Secondary outcomes	

1

Description

Patients' satisfaction with androgenic alopecia recovery

Timepoint

At the beginning of the study (before the start of the intervention) and 6 months after the start of trial

Method of measurement

Visual Analogue Scale

2

Description

Hair regrowth score based on Fotofinder device

Timepoint

At the beginning of the study (before the start of the intervention) and 6 months after the start of trial

Method of measurement

Hair density (hairs/cm²) and Hair diameter (hairs/cm²)

Intervention groups

1

Description

Intervention group 1: minoxidil 5% solution/ The solution would be applied on the head twice a day (morning and night) for 6 months. This solution will be manufactured by the pharmacy of Razi Hospital.

Category

Treatment - Drugs

2

Description

Intervention group 2: spironolactone 2% solution plus minoxidil 5%/ The solution would be applied on the head twice a day (morning and night) for 6 months. This solution will be manufactured by the pharmacy of Razi Hospital.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Razi hospital

Full name of responsible person

Zeinab Aryanian

Street address

Vahdate eslami St. Razi alley. Razi Dermatology Hospital

City

Tehran

Province

Tehran

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1199663911

Phone

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z_aryanian@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Shahin Hamzelou

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Phone

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Email

dr.hamzelou@gmail.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

Nika Kianfar

Position

Post doctorate fellow

Latest degree

Medical doctor

Other areas of specialty/work

Dermatology

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Person responsible for updating data

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nika_kianfar@yahoo.com

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

The data file information of the participants - study protocol - statistical analysis plan - informed consent form will be published after de-identification.

When the data will become available and for how long

The access period starts 6 months after the results are published

To whom data/document is available

Receiving data will be available for researchers working in academic and scientific institutions or people who are also engaged in industry

Under which criteria data/document could be used

In order to conduct scientific studies

From where data/document is obtainable

Dr. Nika Kianfar nika_kianfar@yahoo.com

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

After sending the request by providing a logical reason, the data will be sent to the person within 2 weeks.

Comments