Clinical Trial Protocol
Iranian Registry of Clinical Trials

03 Jun 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)

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+98 21 2285 7201

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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

Public title
Effect of spironolactone and minoxidil solution in treatment of androgenic alopecia
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Aged 18-60 Clinical diagnosis of androgenic alopecia with a dermatologist Have not received any drug for alopecia in the past 12 months
Exclusion criteria:
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
Age
From **18 years** old to **60 years** old
Gender
Both

Phase
2-3
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
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.
Blinding (investigator's opinion)
Double blinded
Blinding description
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.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Tehran University of Medical Sciences
Street address
Vahdate eslami St. - Razi alley. Razi Dermatology Hospital
City
Tehran
Province
Tehran
Postal code
119963911
Approval date
2022-10-01, 1401/07/09
Ethics committee reference number
IR.TUMS.MEDICINE.REC.1401.509

Health conditions studied

1

Description of health condition studied
Androgenic alopecia
ICD-10 code
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
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1199663911
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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
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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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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