Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Preparation and Clinical evaluation of the combined solution of minoxidil, azelaic acid and spironolactone in the treatment of androgenic alopecia

Protocol summary

Study aim
The aim of the present study was to formulate a topical solution of minoxidil, spironolactone, and azelaic acid and its clinical evaluation in androgenic alopecia.

Design
A randomized controlled clinical trial with a parallel group

Settings and conduct
The present study is a two-group clinical trial that will be conducted in Hamedan city in 1404 with the participation of 50 patients with androgenic alopecia. Patients will be randomly divided into two groups (an intervention group and a control group).Intervention group: They will receive a solution containing minoxidil 5%, spironolactone 5%, and azelaic acid 1.5% twice daily for three months.Control group: The patients use a solution containing minoxidil 5% in two sessions for three months.

Participants/Inclusion and exclusion criteria
Age group older than 18 years and diagnosis of androgenetic alopecia and severity of the disease and the individual by dermatologists and hair specialists, as well as the absence of other diseases

Intervention groups
Intervention group: They will receive a solution containing minoxidil 5%, spironolactone 5%, and azelaic acid 1.5% twice daily for three months. Control group: The patients use a solution containing minoxidil 5% in two sessions for three months.

Main outcome variables
Incidence and severity of androgenetic alopecia

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200115046143N3**
Registration date: **2025-10-18, 1404/07/26**
Registration timing: **prospective**

Last update: **2025-10-18, 1404/07/26**
Update count: **0**

Registration date
2025-10-18, 1404/07/26

Registrant information

Name
Seyed Yaser Vafaei

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 81 3426 6353

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2025-10-22, 1404/07/30

Expected recruitment end date
2026-04-20, 1405/01/31

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Preparation and Clinical evaluation of the combined solution of minoxidil, azelaic acid and spironolactone in the treatment of androgenic alopecia

Public title
Preparation and Clinical evaluation of the combined solution of minoxidil, azelaic acid and spironolactone in

the treatment of androgenic alopecia

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Diagnosis of androgenetic alopecia and its severity Informed consent of the patient No specific underlying diseases Absence of other skin diseases

Exclusion criteria:

Sensitivity to soluble components Diabetic patients with heart failure Pregnancy during the study Side effects that are not tolerated by the patient Immune deficiency Malignant diseases

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

Random assignment of the patients to the intervention and control groups through the drawing of lots. To do this, we prepare two sheets and write "intervention" on one sheet and "control" on another. Then, by referring each patient, one of the sheets will be randomly taken and the patient will be assigned to the intervention or control group.

Blinding (investigator's opinion)

Double blinded

Blinding description

The shape of the medications will be perfectly the same in the two groups. Therefore, patients will be unaware of the type of intervention. The physician who will examine the patients will not be aware of the intervention. Therefore, the trial will be run as 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 Hamadan University of Medical Sciences

Street address

Hamadan, Shahid Fahmideh Ave., Hamadan University of Medical Sciences

City

Hamedan

Province

Hamadan

Postal code

38698-65178

Approval date

2025-10-04, 1404/07/12

Ethics committee reference number

IR.UMSHA.REC.1404.566

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

Incidence and severity of Androgenic Alopecia

Timepoint

Before and up to 3 months after the intervention

Method of measurement

World Health Organization Scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: They will receive a solution containing minoxidil 5%, spironolactone 5%, and azelaic acid 1.5% twice daily for three months.

Category

Treatment - Drugs

2

Description

Control group: The patients use a solution containing minoxidil 5% in two sessions for three months.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Sina Farshchian Hospital

Full name of responsible person
Seyed Yaser Vafaei

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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Full name of responsible person
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Grant name

Grant code / Reference number

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

Title of funding source
Hamedan 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
Hamedan University of Medical Sciences

Full name of responsible person
Seyed Yaser Vafaei

Position
Assistant Prophessor

Latest degree
Specialist

Other areas of specialty/work
Medical Pharmacy

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Person responsible for updating data

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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