

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

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

Protocol summary

Registration timing: **prospective**

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.

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

Update count: **0**

Registration date

2025-10-18, 1404/07/26

Design

A randomized controlled clinical trial with a parallel group

Registrant information

Name

Seyed Yaser Vafaei

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 81 3426 6353

Email address

y.vafaei@umsha.ac.ir

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.

Recruitment status

Recruitment complete

Funding source

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

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

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

Scientific title

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

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200115046143N3**

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

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

Street address

Hamadan, Shahid Fahmideh Ave, Hamadan University of Medical Sciences

City

Hamedan

Province

Hamadan

Postal code

38698-65178

Phone

+98 81 3838 1590

Email

y.vafaei@umsha.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Saeed Bashirian

Street address

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

City

Hamedan

Province

Hamadan

Postal code

38698-65178

Phone

+98 81 3838 0717

Email

s_bashirian@umsha.ac.ir

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 Professor

Latest degree

Specialist

Other areas of specialty/work

Medical Pharmacy

Street address

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

City

Hamedan

Province

Hamadan

Postal code

38698-65178

Phone

+98 81 3838 1590

Email

y.vafaei@umsha.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Seyed Yaser Vafaei

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Medical Pharmacy

Street address

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

City

Hamedan

Province

Hamadan

Postal code

6517838695

Phone

+98 81 3838 1590

Email

y.vafaei@umsha.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Seyed Yaser Vafaei

Position

Pharmaceutics Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Medical Pharmacy

Street address

Faculty of pharmacy, Hamadan university of medical science, Shahid Fahmideh ave, Hamadan

City

Hamedan

Province

Hamadan

Postal code

6517838695

Phone

+98 81 3426 6353

Email

y.vafaei@umsha.ac.ir

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