Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of the effectiveness of the combined treatment of topical minoxidil and topical cetirizine solution with topical minoxidil alone in male and female patient with moderate to severe androgenetic alopecia

Protocol summary

Study aim

Comparison of the effectiveness of the combined treatment of topical cetirizine solution and topical minoxidil with topical minoxidil alone in the treatment of androgenetic alopecia.

Design

A clinical trial with a control group, with parallel groups, a blind strain, randomized, phase 3 on 62 patients, simple randomization using random number table method is used for randomization.

Settings and conduct

The number of 62 patients with androgenetic alopecia referring to the medical centers of Isfahan University of Medical Sciences from among the patients who are eligible to enter the study and have consented to participate in the study are randomly divided into two study groups. become First, a complete description of the patient's condition is taken and the patient is placed under photography in 4 standard views. Also, the number of hairs (non-vellus and vellus) on the surface of one square inch and the thickness of the hair are measured and recorded by dermatoscopy. Then the patients in two groups A and B are sent to the pharmacy. They are scheduled on a daily basis and the doctor is not aware of the type of group A and B, and they will be coded at the end of the study.4 months after the use of the topical medication, a re-examination with photography and dermatoscopy was performed, and the satisfaction score of the patients and the doctor was recorded.

Participants/Inclusion and exclusion criteria

People aged 18 to 50 years with androgenetic alopecia without other causes of alopecia and without serious underlying disease or recent systemic steroid use and without sensitivity to cetirizine and minoxidil

Intervention groups

In the intervention group, patients receive minoxidil solution and cetirizine simultaneously, and in the comparison group, minoxidil solution is received alone.

Main outcome variables

Hair thickness, hair density, change of photography score, patient satisfaction

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230308057655N1**
Registration date: **2023-03-20, 1401/12/29**
Registration timing: **prospective**

Last update: **2023-03-20, 1401/12/29**
Update count: **0**

Registration date

2023-03-20, 1401/12/29

Registrant information

Name

Somaye Maleki

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-04-04, 1402/01/15

Expected recruitment end date

2023-11-21, 1402/08/30

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of the effectiveness of the combined treatment of topical minoxidil and topical cetirizine solution with topical minoxidil alone in male and female patient with moderate to severe androgenetic alopecia

Public title
Comparison of the effectiveness of topical minoxidl and cetirizine in androgenetic alopecia
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
All patient with androgenetic alopecia aged 18 to 50 Patient who are willing to participate in trial
Exclusion criteria:
Patient with other types of alopecia Any serious systemic disease Patient who have had a history of hair transplantation in the past History of sensitivity to cetirizine and minoxidil Systemic steroid use for more than 14 days in the last 2 monthes
Age
From **18 years** old to **50 years** old
Gender
Both

Phase
3
Groups that have been masked

- Investigator

Sample size
Target sample size: **62**
Randomization (investigator's opinion)
Randomized
Randomization description
Randomization in the study is a simple random method, in this way, using a computer system, 31 numbers are randomly selected from 1 to 62 for one group (A), and 31 numbers for the other group (B). then based on the order of entry of the patients into the study and the number they get based on the order of entry, which is related to which list, they are entered into one of these two groups (A or B). The pharmacy is aware of whether the intervention group (cetirizine + minoxidil) or the comparison group (minoxidil alone) is A and B and is blinded to the doctor.
Blinding (investigator's opinion)
Single blinded
Blinding description
In order to blind the study, both cetirizine and minoxidil were given to the patients in the form of a solution and in the same packaging as numbers one and two, and the doctor did not know the type of medicine for each patient. (one-way blind method) The doctor secretly sent the patients with numbers A and B to the pharmacy, and only the pharmacist was aware of the type of treatment for these two groups, and at the end of the study and the end of the examinations, the type of treatment for each group will be revealed to the doctor. and B are each cetirizine and minoxidil or minoxidil alone)
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Isfahan University of Medical Sciences
Street address
Sofeh St., Isfahan University of Medical Sciences
City
Isfahan
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Isfehan
Postal code
8174673461
Approval date
2023-01-17, 1401/10/27
Ethics committee reference number
IR.MUI.MED.REC.1401.367

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
The increase in density and thickness of hair
Timepoint
before the start of treatment and 4 months after the start of treatment
Method of measurement
Trichogram and standard photography in 4 views

Secondary outcomes

1

Description
Patient satisfaction score, doctor satisfaction score
Timepoint
The beginning of the study and 4 months after the start of the study
Method of measurement
A 7-point questionnaire to check the level of patient and doctor satisfaction

Intervention groups

1

Description
Intervention group: The intervention group is treated with topical cetirizine and topical minoxidil solution. First, 38 grams of cetirizine powder is prepared from Amin Pharmaceutical Company, then it is prepared by pharmacist in the form of a 1% cetirizine solution in alcohol base and it is provided to patients in a 120 cc solution package. After the initial examination, the patients start taking local treatment in the form of a 1% cetirizine solution once a day along with 5% minoxidil solution of the brand Pak Darou 2 times a day (morning and night) and after 4 months of treatment, re-evaluation and examination will be performed.
Category
Treatment - Drugs

2

Description
The control group was first examined and then treated with minoxidil 5 percent of the brand Pak Darou twice a day in the morning and at night and at the end of 4 months the evaluation and examination will be done again.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Alzahra Hospital
Full name of responsible person
Somayeh Maleki
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Vice President of Technology and Research of Isfahan University of Medicine
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Hazar Jarib St., Isfahan University of Medical Sciences and Health Care Services, Building No. 4 - University Research and Technology Vice-Chancellor
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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
Esfahan 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
Esfahan University of Medical Sciences
Full name of responsible person
Somayeh Maleki
Position
Medical Resident
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Other areas of specialty/work
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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