Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparative study of the combined effect of topical minoxidil and oral spironolactone with the combined effect of topical minoxidil and oral finasteride on female pattern and male pattern hair loss in women referred to Rasool Akram and Firoozgar hospitals in 1400-1401

Protocol summary

Study aim
Evaluation of the efficacy of Minoxidil with Spironolactone in comparison with Finasteride in the treatment of female pattern and male pattern hair loss

Design
A clinical trial with two intervention groups, parallel, randomized, phase 3 on 60 patients, randomized with lottery

Settings and conduct
the study is performed in Firouzgar hospital, Tehran. Patients in the first group use minoxidil solution 2% once a day and spironolactone (100 mg daily in two doses) and patients in the second group use minoxidil solution 2% once a day and finasteride (5 mg per day), 4 months in both groups. For evaluation, at the time of beginning of treatment, 2 and 4 months later, the severity of alopecia is determined by the treating physician based on the Ludwig grade. Another physician, who does not know which group the patient is in, scores the improvement based on clinical imaging as well as dermatoscopic images. The patient's satisfaction with the treatment is also determined. Finally, the statistician analyzes the results of the study.

Participants/Inclusion and exclusion criteria
Inclusion criteria: scalp involvement, aged 15-45 years, satisfaction to participate in the study, ability to follow the patient, normal hormonal tests. Exclusion criteria: having an underlying disease, history of polycystic ovary syndrome, history of treatment in the last two months for the disease, contraindications to the use of spironolactone or finasteride such as pregnancy and lactation, concomitant use of drugs that may interact with the study drugs.

Intervention groups
Group 1: a combination of Minoxidil and Spironolactone.
Group 2: a combination of Minoxidil and Finasteride.

Main outcome variables
The severity of androgenetic alopecia based on Ludwig grade, qualitative and quantitative severity of androgenic alopecia based on clinical and dermatoscopic images

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20211210053343N1**
Registration date: **2021-12-29, 1400/10/08**
Registration timing: **prospective**

Last update: **2021-12-29, 1400/10/08**
Update count: **0**

Registration date
2021-12-29, 1400/10/08

Registrant information

Name
Zeynab Tavana

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-01-05, 1400/10/15

Expected recruitment end date
2022-07-06, 1401/04/15
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparative study of the combined effect of topical minoxidil and oral spironolactone with the combined effect of topical minoxidil and oral finasteride on female pattern and male pattern hair loss in women referred to Rasool Akram and Firoozgar hospitals in 1400-1401

Public title
Comparison of the effect of minoxidil and spironolactone with minoxidil and finasteride in the treatment of Androgenic Alopecia
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
scalp involvement aged 15-45 years satisfaction to participate in the study ability to follow the patient based on the doctor's diagnosis normal hormonal tests
Exclusion criteria:
having an underlying disease history of polycystic ovary syndrome history of treatment in the last two months for the disease contraindications to the use of spironolactone or finasteride such as pregnancy and lactation concomitant use of drugs that may interact with the drugs under study
Age
From **15 years** old to **45 years** old
Gender
Female

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
for each group of the disease, patients with female pattern hair loss and patients with male pattern hair loss, After being selected by available method, patients are divided into two groups by simple randomization, so that among 30 sealed bags, one bag will be randomly selected for each patient. Each bag contains the letter a or b: a for the group receiving Minoxidil and Spironolactone and b for the group receiving Minoxidil and Finasteride.
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Iran University of medical scinces
Street address
Hazrat Rasool Akram hospital, Mansoori avenue, Sattarkhan street, Tehran, Iran
City
Tehran
Province
Tehran
Postal code
1445613131
Approval date
2021-08-04, 1400/05/13
Ethics committee reference number
IR.IUMS.FMD.REC.1400.305

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
severity of alopecia
Timepoint
At the beginning of the study, 2 and 4 months later
Method of measurement
based on Ludwig grade by patient s physician

2

Description
qualitative and quantitative severity of alopecia
Timepoint
At the beginning of the study, 2 and 4 months later
Method of measurement
based on clinical and dermatoscopic images by a blind dermatologist

3

Description
The rate of improvement
Timepoint
2 and 4 months after the beginning of the treatment
Method of measurement
based on patient satisfaction scale

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group 1: Patients in the first group use Minoxidil solution 2% once a day and Spironolactone (100 mg daily in two doses) for 4 months.
Category
Treatment - Drugs

2

Description
Intervention group 2: Patients in the second group use Minoxidil solution 2% once a day and finasteride (5 mg per day) for 4 months.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Hazrat Rasool Akram hospital
Full name of responsible person
Afsaneh Sadeghzadeh Bazargan
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2

Recruitment center
Name of recruitment center
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
Iran 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
Iran University of Medical Sciences
Full name of responsible person
Afsaneh Sadeghzadeh Bazargan

Position
Assistasnt Professor
Latest degree
Specialist
Other areas of specialty/work
Dermatology
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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
Not applicable