Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Comparison of therapeutic effects of 5% minoxidil solution alone with the combination of 5% minoxidil and flutamide solution in patients with androgenic alopecia

Protocol summary

Study aim
Comparison of therapeutic effects of minoxidil solution alone with the combination of minoxidil and flutamide solution in patients with androgenetic alopecia

Design
A randomized double-blinding clinical trial, with the parallel groups

Settings and conduct
In this study, 40 patients with androgenic alopecia will be included and will be randomly divided into two groups. Minoxidil solution will be used in one group and flutamide and minoxidil solution in the other group. Then the severity of hair loss and hair density of patients are evaluated.

Participants/Inclusion and exclusion criteria
Inclusion criteria included the diagnosis of androgenic alopecia by two experienced dermatologists based on Hamilton diagnostic criteria, severity of hair loss in stages 2 to 5 according to Hamilton scale and in stages 1 and 2 according to Ludwig scale, hair loss less than 10 years and patient satisfaction to participate in the study. Exclusion criteria include a history or observation of allergies to any of the minoxidil and flutamide drugs, a history of heart disease and taking antihypertensive drugs, receiving systemic treatment for androgenic alopecia during the 6 months prior to the study, and other types of alopecia, such as Alopecia areata, telogen effluvium, anagen effluvium, and scarring alopecia and any systemic skin disease, and being pregnant or lactating, or postmenopausal women.

Intervention groups
n this study, patients in the first intervention group will receive 1 cc (equivalent to 20 drops) of 5% minoxidil solution twice a day and patients in the second intervention group will receive 1 cc (equivalent to 20 drops) of 2% flutamide + 5% minoxidil solution twice a day. Patients in both groups will take the solutions for 9 months.

Main outcome variables
Hair density; Severity of hair loss

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200825048515N6**
Registration date: **2020-10-07, 1399/07/16**
Registration timing: **prospective**

Last update: **2020-10-07, 1399/07/16**
Update count: **0**

Registration date
2020-10-07, 1399/07/16

Registrant information

Name
Asieh Maghami Mehr

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 31 0000 0000

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asimaghami@yahoo.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-10-22, 1399/08/01

Expected recruitment end date
2021-04-19, 1400/01/30

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of therapeutic effects of 5% minoxidil solution alone with the combination of 5% minoxidil and flutamide solution in patients with androgenic alopecia

Public title
Comparison of the therapeutic effects of minoxidil solution alone with the combination of minoxidil and flutamide solution in patients with androgenic alopecia
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Confirmation of androgenic alopecia by two experienced dermatologists based on Hamilton diagnostic criteria Patient consent to participate in the study The intensity of hair loss in stage 2 to 5 according to Hamilton scale and in stages 1 and 2 according to Ludwig scale The duration of hair loss is less than 10 years
Exclusion criteria:
History or observation of allergies to any of the drugs minoxidil and flutamide History of heart disease and use of antihypertensive drugs Receiving systemic treatment for androgenic alopecia during the 6 months prior to the study Other types of alopecia such as alopecia areata, telogen effluvium, anagen effluvium and scarring alopecia of any systemic cutaneous disease
Age
From **18 years** old to **45 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **40**
Randomization (investigator's opinion)
Randomized
Randomization description
40 eligible patients will be randomly selected. Then, these patients will be randomly encoded using computer software called "Random Allocation" and automatically divided into two groups. The relevant codes will be entered in the raw checklists and each of these checklists will be randomly assigned to one patient and that patient will be randomly assigned to one of the two study groups.
Blinding (investigator's opinion)
Double blinded
Blinding description
The two solutions of minoxidil and the combined solution of flutamide and minoxidil are already prepared by the pharmacist in the same volume and with the same color and shape, and are labeled A and B and will be given to the patients. Therefore, the patient and the researcher will not have any information about the two prescribed solutions.
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
Hezar Jarib Ave, Azadi Square.
City
Isfaha
Province
Isfehan
Postal code
8174673461
Approval date
2019-07-03, 1398/04/12
Ethics committee reference number
IR.MUI.MED.REC.1398.562

Health conditions studied

1

Description of health condition studied
Androgenic alopecia
ICD-10 code
L64.9
ICD-10 code description
Androgenic alopecia, unspecified

Primary outcomes

1

Description
Hair density
Timepoint
Pre-and post-intervention
Method of measurement
Hair polarizer

2

Description
Severity of hair loss
Timepoint
Pre-and post-intervention

Method of measurement
By a skilled physician based on Hamilton-Norwood scale for male pattern hair loss and Ludwig scale for female pattern hair loss

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Patients in the first intervention group will take 1 cc (equivalent to 20 drops) of 5% minoxidil solution twice a day for 9 months.
Category
Treatment - Drugs

2

Description
Intervention group: Patients in the second intervention group will take 1 cc (equivalent to 20 drops) of the combined solution of 2% flutamide and 5% minoxidil twice a day for 9 months.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Al-Zahra Hospital
Full name of responsible person
Gita Faghihi
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Esfahan University of Medical Sciences
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Shaghayegh Haghjoo Javanmard
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Isfahan 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
Gita Faghihi
Position
Professor
Latest degree
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
There is no further information
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available