

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 May 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 androgenic 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

In 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)

Phone

+98 31 0000 0000

Email address

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

Isfahan

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

Street address

Soffe Blvd, Isfahan

City

Isfahan

Province

Isfahan

Postal code

8174675731

Phone

+98 31 3620 2020

Email

g_faghighi@med.mui.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Shaghayegh Haghjoo Javanmard

Street address

Vice Chancellor for Research, School of Medicine,
Hezar Jarib Street, Isfahan.

City

Isfahan

Province

Isfahan

Postal code

8174673461

Phone

+98 31 3668 8597

Email

dean@med.mui.ac.ir

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

Specialist

Other areas of specialty/work

Dermatology

Street address

Dermatology Department, Al-Zahra Hospital, Hezar Jarib Street

City

Isfahan

Province

Isfahan

Postal code

8174675731

Phone

+98 31 3620 2020

Email

g_faghighi@med.mui.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Gita Faghihi

Position

Professor

Latest degree

Specialist

Other areas of specialty/work

Dermatology

Street address

Dermatology Department, Al-Zahra Hospital, Hezar Jarib Street

City

Isfahan

Province

Isfahan

Postal code

8174675731

Phone

+98 31 3620 2020

Email

g_faghihi@med.mui.ac.ir

Person responsible for updating data**Contact****Name of organization / entity**

Esfahan University of Medical Sciences

Full name of responsible person

Maedeh Sadat Hosseini

Position

Non-faculty physician

Latest degree

Medical doctor

Other areas of specialty/work

Dermatology

Street address

Robot Street

City

Isfahan

Province

Isfahan

Postal code

8139946553

Phone

+98 31 3442 7529

Email

maedeh.hosseini71@yahoo.com

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