Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Comparing the efficacy and safety of oral finasteride with oral dutasteride in moderate to severe male androgenetic alopecia

Protocol summary

Study aim
Evaluation of the effect of oral finasteride in comparison with oral dutasteride in treatment of male androgenetic alopecia.

Design
Community based, parallel group, single blind, randomized trial, phase 3 on 80 patients. Random allocation software is used for randomization.

Settings and conduct
In this study, 80 male patients with moderate to severe androgenetic alopecia referred to medical centers of Isfahan University of Medical Sciences are enrolled after completing a thorough explanation of the course and purpose of the study, as well as physical examination, complete history of the disease and obtaining informed consent. Patients are randomly assigned to two groups. The first group receives oral finasteride 1 mg/day and the second group receives oral dutasteride 0.5 mg/day. After 25 weeks of treatment, patients are compared and evaluated by standard photography and trichogram obtained at the beginning and end of treatment.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Male patients diagnosed with moderate to severe androgenetic alopecia who do not have any of the followings (Non-inclusion criteria): any serious systemic disease, psoriasis or lichen planus; other types of alopecia; any andrological condition known to affect semen parameters and male fertility; history of hair transplant; history of breast cancer or male infertility in first degree relatives; received any treatment for alopecia in the past three months. Exclusion criteria: Serum levels of prostate specific antigen (PSA) greater than 2 ng/ml; Abnormal liver function tests (except chronic stable hepatitis B and C).

Intervention groups
Intervention group 1: These patients receive oral finasteride 1 mg per day. Intervention group 2: These patients receive oral dutasteride 0.5 mg per day.

Main outcome variables
Hair thickness; number of hair; change of photographic score; patient satisfaction score

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20231025059850N1**
Registration date: **2024-01-27, 1402/11/07**
Registration timing: **registered_while_recruiting**

Last update: **2024-01-27, 1402/11/07**
Update count: **0**

Registration date
2024-01-27, 1402/11/07

Registrant information

Name
reza makhmali

Name of organization / entity

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-11-21, 1402/08/30

Expected recruitment end date
2024-11-20, 1403/08/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparing the efficacy and safety of oral finasteride with oral dutasteride in moderate to severe male androgenetic alopecia

Public title
Comparing The Effect of Finasteride With Dutasteride on Hair Growth in Male Androgenetic Alopecia

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Male patients diagnosed with moderate to severe androgenetic alopecia (grade 3, 4, 5 Hamilton-norwood scale) Do not have any of the followings (Non-inclusion criteria): any serious systemic disease, psoriasis or lichen planus; other types of alopecia (including anagen effluvium, telogen effluvium and scarring alopecia); any andrological condition known to affect semen parameters and male fertility (including varicocele, cryptorchidism, testicular cancer, testicular trauma, orchitis, urinary tract infection; previous chemotherapy or radiotherapy); history of hair transplant; history of breast cancer or male infertility in first degree relatives. Patients who have not received any treatment for alopecia in the past three months

Exclusion criteria:
Serum levels of prostate specific antigen (PSA) greater than 2 ng/ml Abnormal liver function tests (except chronic stable hepatitis B and C)

Age
From **20 years** old to **50 years** old

Gender
Male

Phase
3

Groups that have been masked

- Investigator

Sample size
Target sample size: **80**

Randomization (investigator's opinion)
Randomized

Randomization description
simple randomization using random allocation software.

Blinding (investigator's opinion)
Single blinded

Blinding description
Our study is single blinded in which the type of drug administered is unclear to investigator.

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
Isfahan University of Medical Sciences, Hezarjarib St.

City
Esfahan

Province
Isfehan

Postal code
8174673461

Approval date
2023-10-20, 1402/07/28

Ethics committee reference number
IR.MUI.MED.REC.1402.177

Health conditions studied

1

Description of health condition studied
Androgenetic alopecia

ICD-10 code
L64.9

ICD-10 code description
Androgenic alopecia, unspecified

Primary outcomes

1

Description
Number of hair follicles

Timepoint
Obtaining standard photographic pictures before the intervention and 25 weeks after the intervention

Method of measurement
A 7-point questionnaire developed by a physician based on the comparison of standard photographic pictures (checking the thickness and number of hairs).

2

Description
Hair growth rate

Timepoint
perform scalp dermoscopy before the intervention and 25 weeks after the intervention

Method of measurement
A 7-point questionnaire developed by a physician based on the comparison of phototrichograms (checking the thickness and number of hairs).

3

Description
Patient satisfaction score

Timepoint
before the intervention and 25 weeks after the intervention which is the end of the study
Method of measurement
مقیاس آنالوگ بصری

Secondary outcomes

1

Description
Sexual dysfunction
Timepoint
Before the intervention and 25 weeks after the intervention which is the end of the study
Method of measurement
Interview with the patient

2

Description
Erectile dysfunction
Timepoint
Before the intervention and 25 weeks after the intervention which is the end of the study
Method of measurement
Interview with the patient

3

Description
Any side effects following consumption of finasteride and dutasteride
Timepoint
Every 3 months
Method of measurement
Interview with the patient

Intervention groups

1

Description
Intervention group 1: Oral consumption of finasteride 1 mg daily for 25 weeks
Category
Treatment - Drugs

2

Description
Intervention group 2: Oral consumption of dutasteride 0.5 mg daily for 25 weeks
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
dermatology clinic, Al-Zahra University Hospital
Full name of responsible person
Nazila Poostiyan
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2

Recruitment center
Name of recruitment center
Sedighe Tahereh Comprehensive Medical and Rehabilitation Center, Skin Disease Research Center
Full name of responsible person
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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
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
Nazila Poostiyan
Position
Assistant Professor
Latest degree
Specialist
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Person responsible for updating data

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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
No information
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