

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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+98 31 3329 7212

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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

Isfahan

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

Street address

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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

Nazila Poostiyan

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Khoram St.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Gholamreza Askari

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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

Other areas of specialty/work

Dermatology

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Esfahan University of Medical Sciences

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Latest degree

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

Esfahan University of Medical Sciences

Full name of responsible person

reza makhmali

Position

researcher

Latest degree

Medical doctor

Other areas of specialty/work

Dermatology

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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