Clinical Trial Protocol
Iranian Registry of Clinical Trials

01 Jul 2026

The Efficacy and side effects of oral dutasteride in the treatment of female pattern androgenetic alopecia compared with oral spironolactone in one sided clinical trial

Protocol summary

Study aim
The study of efficacy and complications of oral dutasteride in the treatment of patients with androgenetic alopecia

Design
Clinical trial with control group, parallel blind, randomized, phase 3 on 40 patients for 6 months.Randomization was carried out using block randomization

Settings and conduct
Patients referred to Razi Hospital are divided into two groups and randomly entered into one of the two groups. Before the treatment, the areas of the head that have the least density of hair in the vertex are determined by a tattoo on the scalp by a dermatologist, and before the start and during the treatment intervals and after that, we calculate the number of hairs in the same area using a trichoscope. And by taking pictures of the patients, a comparison is made. The specified area is selected in the minimum density area, and in the completely hairless areas, the edge of the hairless area is used. Patients are evaluated in each visit with global clinical photography and quantitative digital videotrichoscopic assessment.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Female patients with androgenetic alopecia (18-55 years old) Exclusion criteria: 1) Intention to get pregnant 2) Sensitivity to the studied drug 3) History of breast cancer in the patient or first-degree relatives 4) Usage of other alopecia treatments in the past six months 5) having any skin or systemic diseases that affect hair growth

Intervention groups
Study group: taking oral Dutasteride 0.5 mg daily for 6 months. Control group: taking oral spironolactone 100 mg daily for 6 months.

Main outcome variables
Sex؛ Age؛ Alopecia grade؛ Previous treatments؛ Duration of previous treatment؛ Therapeutic response؛ Total hair density (frontal and vertex) ؛Patient's quality of life؛ Number of villus and terminal hairs؛ Hair thickness؛ Complications of treatment

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20231119060107N1**
Registration date: **2024-01-08, 1402/10/18**
Registration timing: **prospective**

Last update: **2024-01-08, 1402/10/18**
Update count: **0**

Registration date
2024-01-08, 1402/10/18

Registrant information

Name
hussein kezzo

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 901 111 7513

Email address
h_kezzo@yahoo.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2024-02-19, 1402/11/30

Expected recruitment end date
2024-07-20, 1403/04/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Efficacy and side effects of oral dutasteride in the treatment of female pattern androgenetic alopecia compared with oral spironolactone in one sided clinical trial

Public title

The Efficacy of oral dutasteride in the treatment of female pattern androgenetic alopecia

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Androgenitic alopecia female patients

Exclusion criteria:

History of breast cancer Usage of another AGA treatment in the past 3 months Pregnancy or a plan to get ptegnant in the next year Smoking or alchohol addiction Drug reaction to dutasteride or spironolactone History of hair transplant History of any dermatologic or systemic disease that affect hair

Age

From **18 years** old

Gender

Female

Phase

3

Groups that have been masked

- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

block randomization we have Ten envelopes (blocks) Each envelope containing four papers (two Dutasteride, two spironolactone) to determine every new patient's group, an envelope is selected randomly then a paper is randomly picked from the envelope which determines whether the patient will be in the study group or control group.

Blinding (investigator's opinion)

Single blinded

Blinding description

The principal investigator who is responsible for grading the degree of baldness before and after treatment to photographic images and analysis of tricoscopy images is not aware of the medication used by the patient

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committees of School of Medicine, Tehran University of Medical Sciences

Street address

School of medicine, Pour sina street, Qods street, Enghelab street,Tehran

City

Tehran

Province

Tehran

Postal code

1461884513

Approval date

2023-08-20, 1402/05/29

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1402.269

Health conditions studied

1

Description of health condition studied

Androgenitic alopecia

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Hair density increase in the vertex area

Timepoint

0, 3 months after treatment , 6 months after treament

Method of measurement

Trichoscopy report

2

Description

Hair thickness increase

Timepoint

0, 3 months after treatment , 6 months after treament

Method of measurement

Tricoscopy report

Secondary outcomes

1

Description

Alopecia grade

Timepoint

0, 3 months after treatment , 6 months after treament

Method of measurement

Sinclair scale

2

Description

Treatment response

Timepoint

3 months after treatment , 6 months after treament

Method of measurement

Questionnaire

3

Description

Patient quality of life

Timepoint

0, 3 months after treatment , 6 months after treament

Method of measurement

Dermatology life Quality Index questionnaire

4

Description

Drug complications

Timepoint

1 month after treatment, 3 months after treatment , 6 months after treament

Method of measurement

Questionnaire

5

Description

Villus and terminal hair number

Timepoint

0, 3 months after treatment , 6 months after treament

Method of measurement

Trichoscopy report

Intervention groups

1

Description

Intervention group: patients prescribed oral dutasteride 0.5 mg per day for 6 months

Category

Treatment - Drugs

2

Description

Control group: patients prescribed oral spironolactone 100 mg per day for 6 months

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Razi hospital

Full name of responsible person

hussein kezzo

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http://razihos.tums.ac.ir/en/Home

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr Ali Akbari Sari

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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

Tehran 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
Tehran University of Medical Sciences
Full name of responsible person
Dr Ifa Etesami
Position
Assistant Professor Of Dermatology
Latest degree
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Not applicable
Title and more details about the data/document
Fotofinder and photography gallery in razi center
When the data will become available and for how long
After completing the study and for one year
To whom data/document is available
Razi hospital residents and other recearch centers students
Under which criteria data/document could be used
For research purposes and with respect to patiensts privacy
From where data/document is obtainable
Dr ifa itesami Ifa.etesami@gmail.com
What processes are involved for a request to access data/document
Contact razi hospital research center Ifa.etesami@gmail.com
Comments