Clinical Trial Protocol
Iranian Registry of Clinical Trials

31 Oct 2026

Studying and preparig semi-solid formulations of Finastride and Clinical evaluation of optimal form in the treatment of Hirsutism

Protocol summary

Summary

The main purpose of the study is treatment of hirsutism with topical formulation of systemic drug to lessen the side effects. Also this formulation is cheaper and more available than other treatments for this disease. The duration of this randomized, double blinded study that is controlled with placebo is 6 months and is under observation of a dermatologist. Women after puberty that have hirsutism criteria (based on Ferriman-Gullway scoring system and physical examination and hormonal lab tests) and no history of other disease with an appearance like hirsutism and do not use any other drugs, after signing a written consent are divided randomly in 2 groups; treatment group (with finasteride) and control group (with placebo). The number of patients in each group is 15. The patients are visited a week after usage of the drug and then every one month and a photograph is taken from the site that the formulation is used on it and the amount of response to the treatment and satisfactory of the physician and the patient is recorded. After 6 months the results are compared .If possible at the end of the study (after 6 months) a blood sample for detecting the drug is achieved from the patients in the treatment (interventional) group.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013072214106N1**
Registration date: **2013-09-11, 1392/06/20**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2013-09-11, 1392/06/20

Registrant information

Name
Reza Tahvilian
Name of organization / entity
Kermanshah University of Medical Sciences
Country
Iran (Islamic Republic of)
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rtahvilian@kums.ac.ir

Recruitment status

Recruitment complete

Funding source

Kermanshah University of Medical Sciences

Expected recruitment start date

2013-08-23, 1392/06/01

Expected recruitment end date

2013-10-23, 1392/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Studying and preparig semi-solid formulations of Finastride and Clinical evaluation of optimal form in the treatment of Hirsutism

Public title

Effect of topical application of finasteride in the treatment of hirsutism in women

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criterion: women after puberty that have hirsutism based on Ferriman-Gallwey scoring system. Exclusion criteria: 1. The patient uses any other drugs. 2.

History of other disease with an appearance like hirsutism. 3. The patient is will less to continue participating in this study.

Age
From **18 years** old to **48 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **30**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Kermanshah University of Medical Science

Street address
Shahid Beheshti Street, Kermanshah

City
Kermanshah

Postal code

Approval date
2013-07-10, 1392/04/19

Ethics committee reference number
14955

Health conditions studied

1

Description of health condition studied
Hirsutism

ICD-10 code
L68.0

ICD-10 code description
Hirsutism

Primary outcomes

1

Description
Severity of hirsutism

Timepoint
First day - 1 week later- every one month untill 6 months later

Method of measurement
Ferriman-Gullway score

Secondary outcomes

1

Description
Acne

Timepoint
First day - 6 months later

Method of measurement
Based on physician's discription

Intervention groups

1

Description
Interventional group: Finasteride, 0.25% topical gel, twice daily for six months

Category
Treatment - Drugs

2

Description
Control group: placebo, placebo topical gel, twice daily for six months

Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Haj Daee Clinic

Full name of responsible person
Dr. Ali Ebrahimi

Street address
Kermanshah - Haj Daee Clinic

City
Kermanshah

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Kermanshah Univesity of Medical Science,Research vice-presidency

Full name of responsible person

Dr. Farid Najafi

Street address

Kermanshah, Shahid Beheshti Street

City

Kermanshah

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Kermanshah Univesity of Medical Science,Research vice-presidency

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Sahar Masoud

Position

student of Pharmacy

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty