

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Jul 2026

Comparison of therapeutic effects of oral Flutamide and Cyproteron compound on female moderate acne

Protocol summary

Summary

Study population in this clinical trial study were females with acne who were not pregnant or lactating, lacked hepatic disease and didn't use OCPs or anti androgenic drugs. Sample size was calculated to be 30 for each group. Six months long treatment regimen was used. Improvement of acne and decrease in dermal fat was assessed every two months. Diagnosis was made by a dermatologist and assessments were made by someone else in dermatology specialty clinic. Patients in the intervention group received oral Flutamide 250 mg daily and control (standard treatment) group received Cyproterone compound one tablet daily (21 days over one month). Both groups received topical Clindamycin complementary treatment twice daily.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138904134310N1**

Registration date: **2007-02-20, 1385/12/01**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2007-02-20, 1385/12/01

Registrant information

Name

Hassan Adalatkhah

Name of organization / entity

Ardebil University of medical sciences

Country

Iran (Islamic Republic of)

Phone

+98 914 308 6490

Email address

h.edalatkhah@arums.ac.ir

Recruitment status

Recruitment complete

Funding source

"Ardebil medical university", Deputy for research

Expected recruitment start date

2007-02-20, 1385/12/01

Expected recruitment end date

2008-02-20, 1386/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of therapeutic effects of oral Flutamide and Cyproteron compound on female moderate acne

Public title

Therapeutic effects of flutamide on female acne

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion: 1-Women who having moderate acne 2- age>16 Exclusion: 1-Pregnancy 2- hepatic diseases 3- Using OCPs and androgenic drugs

Age

From **16 years** old

Gender

Female

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Single blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ardebil Medical University

Street address

Deputy of research, Daneshgah street, Ardebil

City

Ardebil

Postal code

56189/53141

Approval date

empty

Ethics committee reference number

number-1

Health conditions studied**1****Description of health condition studied**

Acne vulgaris

ICD-10 code

L70.0

ICD-10 code description

Acne vulgaris

Primary outcomes**1****Description**

Count of acne lesions

Timepoint

2 months

Method of measurement

Counting the lesions

Secondary outcomes**1****Description**

Reduction of sebum

Timepoint

2 months

Method of measurement

Mexameter

2**Description**

Side effects of drug

Timepoint

2 months

Method of measurement

Clinical examination

3**Description**

Degree of resolution of acne lesions

Timepoint

2 months

Method of measurement

Counting of acne lesion

Intervention groups**1****Description**

Flutamide 250 mg daily +topical clindamicin 1% for six months

Category

Treatment - Drugs

2**Description**

Cyproteron compound+topical clindamicin 1% for 6 months

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Babak dermatology clinic

Full name of responsible person

Edalatkhah

Street address

Sarcheshmeh circus, Ardebil

City

Ardebil

Sponsors / Funding sources**1****Sponsor**

Name of organization / entity

Ardebil Medical University

Full name of responsible person

Dr Mehrdad Mirzarahimi

Street address

Deputy of research, Ardebil medical university,
Daneshgah street, Ardebil

City

Ardebil

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Ardebil Medical University

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

Ardebil medical University

Full name of responsible person

Dr. Mohsen Arzanlou

Position

Research deputy manager -PhD

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

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Position

Dermatologist

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Person responsible for updating data

Contact

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Rasoul lotfollahzadeh

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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