

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 May 2026

Effects of Cyproterone Compound Combined with flutamide in females severe acne

Protocol summary

Summary

This study was a interventional study, The aim was study of combination effect of ciprotrone compound & flutamide in females with severe acne. Inclusion criteria was Females with severe acne and Exclusion criteria were: pregnancy; breastfeeding; liver disease; receiving anti acne drugs; OCP & spironolacton in last 2 months. population study of group were females with severe acne. sample size was 30 person. The study period was 6 months. At this period, patients were received 125mg/day flutamide combined with cyproteron compound one pill/day, 21 days a month and 1% topical clindamicine Twice a day. the primary outcome was reduction in acne counting that conducted with counting acne lesions and measurement of acne severity index.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201302164310N8**

Registration date: **2014-04-28, 1393/02/08**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2014-04-28, 1393/02/08

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

Islamic Azad University of Ardabil

Expected recruitment start date

2011-01-20, 1389/10/30

Expected recruitment end date

2012-01-20, 1390/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of Cyproterone Compound Combined with flutamide in females severe acne

Public title

Effects of Cyproterone Compound Combined with flutamide in females severe acne

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criterion: females that had severe acne.

Exclusion criteria: pregnancy; breastfeeding; liver disease; receiving anti acne drugs; OCP & spironolacton in last 2 months.

Age

No age limit

Gender

Female

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: 30

Randomization (investigator's opinion)

N/A

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

Not blinded

Blinding description**Placebo**

Not used

Assignment

Single

Other design features**Secondary Ids**

empty

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

Ardabil University of Medical Science

Street address

Ardabil University of Medical Science, Daneshgah st, Ardabil

City

Ardabil

Postal code

04515518939

Approval date

2008-05-10, 1387/02/21

Ethics committee reference number

arums.re.1385.23

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**

decrease in acne lesions

Timepoint

onset of study & 60th, 120th, 180th of study

Method of measurement

lesions counting

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

Patients` satisfaction

Timepoint

Every two months

Method of measurement

Questionnaire

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

Intervention was therapeutic by drug. The study had only one intervention group. Patients were received 125mg/day oral flutamide tablets dual with cyproterone compound pills, one tablet/day, 21 days a month and 1% clindamycin twice daily.

Category

Treatment - Drugs

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

Dermatology Clinic

Full name of responsible person

Edalatkhah Hasan

Street address

Babak Building, Shams Alley, Sracheshmeh St., Ardabil

City

Ardabil

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Ardabil University of Medical Science

Full name of responsible person

Hadi Peeri

Street address

End of Daneshgah St. Administrative building of University of Medical Science, Ardabil

City

Ardabil

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Ardabil University of Medical Science

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

Ardabil University of Medical Science

Full name of responsible person

Golmohammadi . Ghasem

Position

PhD in anatomy, Faculty assistant

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Edalatkhah Hasan

Position

Dermatologist , Faculty member

Other areas of specialty/work

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Person responsible for updating data

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Name of organization / entity

Medical Faculty

Full name of responsible person

Edalatkhah Hasan

Position

Dermatologist , Faculty member

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