Clinical Trial Protocol
Iranian Registry of Clinical Trials

13 Jul 2026

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

Protocol summary

Summary

Study population in this clinical trial study were females with triad of : acne, hirsutism and androgenetic alopecia. If you were not pregnant and lactating or planning pregnancy to 9 months with no contraindications with other medications based on the questionnaire were entered into the study. The sample size was calculated for each group of 15 people. 3 months of treatment and patient evaluation are calculated based on the Total Acne lesion Count(TLC) and acne severity index (ASI) for each patient at baseline, three months and one month after the end of treatment, done. Diagnosis was done by a dermatologist, but the form and physical examination the patient was done by someone else in the dermatology clinic. The first group was treated with decuttane - isotretinoin 20 mg daily 1 tablet and the second group Cyproterone compound (Month 21) received. Also, both equally daily, concurrently treated with azithromycin 250 mg capsules three times a week and once a day solution erythromycin 4% and oil-free sunscreen and soap were TCC.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013110315246N1**
Registration date: **2013-12-14, 1392/09/23**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2013-12-14, 1392/09/23

Registrant information

Name

Kioumars Jamshidi

Name of organization / entity

Isfahan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 31 1777 2134

Email address

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Recruitment status

Recruitment complete

Funding source

Isfahan University of Medical Sciences

Expected recruitment start date

2012-04-18, 1391/01/30

Expected recruitment end date

2014-02-19, 1392/11/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

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

Public title

Acne cure rate in patients Hyperandrogenism with two drugs of Decuttane and CYPROTERONE COMPOUND .

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: age between 14-45 years old; besides acne hirsutism (Ferriman & Gallwey score greater than or equal to 4) and Ludwing grade one or higher female androgenetic alopecia; absence of contraindications to treatment with tablets decuttane and CYPROTERONE COMPOUND based on questionnaire; not wanting to at least 9 months of pregnancy, or breast-feeding;

individual patients signed a consent form Exclusion criteria: drug allergy; pregnancy or lactation; uncooperative patient or patient's consent to continue reading.

Age
From **14 years** old to **45 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
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Isfahan University of Medical Sciences Ethics Committee

Street address
Deputy of research of isfahan university of medical science, hezarjerib street, Isfahan

City
Isfahan

Postal code

Approval date
2012-04-17, 1391/01/29

Ethics committee reference number
291042

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
Improvement of acne vulgaris lesions

Timepoint
Baseline, three months and one month after the end of treatment.

Method of measurement
Indices are calculated based on the Total Acne lesion Count(TLC) and acne severity index (ASI) for each patient

Secondary outcomes

1

Description
Side effects of drug

Timepoint
Every 6 weeks

Method of measurement
clinical evaluation-liver function test and lipid profile

Intervention groups

1

Description
decuttane - isotretinoin 20 mg daily + Azithromycin 250 mg capsules three times a week, erythromycin solution of 4% once a day, oil-free sunscreen and Tcc soap three months

Category
Treatment - Drugs

2

Description
Cyproterone Compound + Azithromycin 250 mg capsules three times a week, erythromycin solution of 4% once a day, oil-free sunscreen and Tcc soap three months

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Alzahra hospital dermatology clinic

Full name of responsible person
Dr. Kioumars Jamshidi

Street address
dermatology group,Alzahra hospital,Isfahan

City
Isfahan

2

Recruitment center
Name of recruitment center
Noor and Aliasghar Hospitals dermatology clinics
Full name of responsible person
Dr. Kioumars Jamshidi
Street address
dermatology group,Alzahra hospital,Isfahan
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3

Recruitment center
Name of recruitment center
Segighe Tahere Hospital dermatology clinic
Full name of responsible person
Dr. Kioumars Jamshidi
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dermatology group,Alzahra hospital,Isfahan
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Isfahan University of Medical Sciences
Full name of responsible person
Dr. Ebrahim Esfandiari
Street address
Isfahan university of medical science,Hezar jerib street,Isfahan
City
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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
Isfahan University of Medical Sciences
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
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Full name of responsible person
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Person responsible for scientific inquiries

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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