Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Comparison of terapeutic effects of Flutamide and Doxicyclin on moderate acne among females

Protocol summary

Summary

This clinical trial study was conducted on melassma female patients with moderate acne who lacked hepatic disease and were not pregnant or breastfeeding and didn't receive OCPs or antiandrogenic drugs. Sample size was estimated to be 30 for each group. Patient allocated randomly to study groups. Diagnosis is made by one dermatologist and further data collection, evaluation and counting lesions was done by another person. Prescriptions were delivered in sealed envelopes by a nurse staff. Trial group received 250 mg daily flutamide and control group received 100 mg daily doxyciline. Both groups received topical clindamicine. CBC tests were done for trial group before treatment, one month and 4 months after treatment. Evaluation of the patient’s condition were done every two months .To get this result numbers of lesions were counted , and sebum reduction was evaluated by Mexameter, and finally patients satisfaction was evaluated by questionnaire.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138905044310N3**
Registration date: **2010-07-26, 1389/05/04**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2010-07-26, 1389/05/04

Registrant information

Name
Hassan Adalatkhah
Name of organization / entity
Ardebil University of medical sciences
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Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source
Ardebil Medical University

Expected recruitment start date

2007-02-14, 1385/11/25

Expected recruitment end date

2008-07-15, 1387/04/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of terapeutic effects of Flutamide and Doxicyclin on moderate acne among females

Public title

Oral flutamide effects on female acne

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: 1- Female sex 2- Moderate acne 3- Age above 16 4- Having melassma Exclusion criteria 1- Pregnancy and breastfeeding 2- Hepatic disease 3- Taking OCPs or antiandrogenic drugs

Age

No age limit

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)

Not 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

Daneshgah street, Ardebil medical university

City

Ardebil

Postal code

Approval date

empty

Ethics committee reference number

Number-3

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

Acne lesion improvment

Timepoint

Every 2 months

Method of measurement

Count of the lesions

Secondary outcomes

1

Description

Side effects of drug

Timepoint

2 months

Method of measurement

Clinical examination

2

Description

Reduction of sebum

Timepoint

2 months

Method of measurement

Mexameter

3

Description

patient satisfaction

Timepoint

2 Months

Method of measurement

questionnaire

Intervention groups

1

Description

Flutamide250 mg daily + topical clindamicin 1% for six months

Category

Treatment - Drugs

2

Description

Doxicyclin 100 mg daily + topical clindamicin 1% for six months

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Babak dermatology clinic

Full name of responsible person

Hasan Edalatkhah

Street address

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 University of medical sciences
Full name of responsible person
Hasan Edalatkhah
Position
MD, Specialty degree in dermatology
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Person responsible for scientific inquiries

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Person responsible for updating data

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Rasoul Lotfollahzadeh
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Web page address
www.arums.ac.ir

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