

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

Comparison of therapeutic effects of Flutamide and Doxycyclin on moderate acne among females

Protocol summary

Summary

This clinical trial study was conducted on melasma 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 doxycycline. 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

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

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 therapeutic effects of Flutamide and Doxycyclin 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 melasma Exclusion criteria 1- Pregnancy and breastfeeding 2- Hepatic disease 3- Taking OCPs or antiandrogenic drugs

Age

No age limit

Gender

Female

Phase

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

Other areas of specialty/work**Street address**

Emam khomayni hospital, Ardebil

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Postal code**Phone**

+98 45 1225 1401

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Web page address

Person responsible for scientific inquiries

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Full name of responsible person

Hasan Edalatkhah

Position

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Person responsible for updating data

Contact**Name of organization / entity**

Ardebil university of medical sciences

Full name of responsible person

Rasoul Lotfollahzadeh

Position

Research officer

Other areas of specialty/work**Street address****City****Postal code****Phone**

+98 45 1551 0061

Fax**Email****Web page address**

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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