

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Aug 2026

Comparasion therapiutic effects of oral Erythromycin along with low dose oral Isotretinoin and oral Erythromycin and low dose Flutamide versus Doxycyclin in female severe acne vulgaris .

Protocol summary

Summary

This research was a single blind and randomized study. The aim was comparison of therapeutic effects of oral Erythromycin along with low dose oral Isotretinoin and oral Erythromycin and low dose Flutamide versus Doxycyclin in female severe acne vulgaris. Inclusion criterion was females with severe acne & Exclusion criteria were: breastfeeding; pregnancy; tending to pregnancy; liver disease; hyperlipidemia; receiving anti acne drugs; contraceptive's; spironolacton in last 2 month. Population study of group was females with severe acne. Sample size was 90 (30 per group).The first intervention group received Erythromycin 400mg per 12 hours along with oral Isotertinoin 20 ml in 2 alternate days. The second intervention group received Erythromycin 400 mg per 12 hours along with Flutamide 65 mg per day. Control group, received Doxycyclin capsules 100 mg per 12 hours. Primary outcome was reduction of acne lesions count. That conducted with acne lesions counting and measurement of acne severity index.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201104094310N6**
Registration date: **2014-04-19, 1393/01/30**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2014-04-19, 1393/01/30

Registrant information

Name

Hassan Adalatkhah

Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Ardabil University of Medical Sciences

Expected recruitment start date

2013-09-20, 1392/06/29

Expected recruitment end date

2014-02-18, 1392/11/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparasion therapiutic effects of oral Erythromycin along with low dose oral Isotretinoin and oral Erythromycin and low dose Flutamide versus Doxycyclin in female severe acne vulgaris .

Public title

Comparasion of therapiutic effects of oral Erythromycin along with low dose oral Isotretinoin and oral Erythromycin and low dose Flutamide versus Doxycyclin in female severe acne vulgaris.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criterion: females with severe acne. Exclusion criteria: pregnancy; breastfeeding; liver disease; hyperlipidemia; receiving anti acne drugs; OCP pills; spironolacton in last 2 months.

Age

No age limit

Gender

Female

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: 90

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

Ardabil University of Medical Science

Street address

Daneshgah St. , Ardabil

City

Ardabil

Postal code

Approval date

2013-09-15, 1392/06/24

Ethics committee reference number

arums.rec,92.28

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 of acne leasions

Timepoint

Onset of study & 30th & 60th day's of study

Method of measurement

Observation

Secondary outcomes

empty

Intervention groups

1

Description

Control group received 100 ml oral daxycycline every 12 hours during 2 mounths.

Category

Treatment - Drugs

2

Description

First intervention group(the group that received oral eritromycin and oral isotretinoin),this group received 800 ml of oral eritromycin (400 ml/BID) and 20 ml oral isotretinoin every 48 hours during 2 mounths.

Category

Treatment - Drugs

3

Description

Second intervention group received 800 ml oral eritromycin a day (400 ml/BID) and 65 ml oral flutamid a day during 2 mounth.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Dermatology Clinic

Full name of responsible person

Hasan Edalatkhah

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Babak Building,Shams Alley ,Sracheshmeh St.,Ardabil

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Ardabil

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ardabil University of Medical Science
Full name of responsible person
 Dr. Ghasem Golmohammadi
Street address
 Daneshgah St.
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
 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

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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