

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

01 Jun 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

Ardebil University of medical sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 914 308 6490

##### Email address

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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 month.

##### **Category**

Treatment - Drugs

### **Recruitment centers**

#### **1**

##### **Recruitment center**

###### **Name of recruitment center**

Dermatology Clinic

###### **Full name of responsible person**

Hasan Edalatkhah

###### **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**

Dr. Ghasem Golmohammadi

**Street address**

Daneshgah St.

**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 Sciences

**Full name of responsible person**

Dr. Ghasem Golmohammadi

**Position**

PhD in anatomy

**Other areas of specialty/work**

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## Person responsible for scientific inquiries

**Contact**

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Ardabil University of Medical Sciences

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Dr. Hasan Edalatkhah

**Position**

Dermatologist , Faculty membe

**Other areas of specialty/work**

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## Person responsible for updating data

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**Position**

Dermatologist

**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*