Clinical Trial Protocol
Iranian Registry of Clinical Trials

12 Jun 2026

Evaluation the effect of isotretinoin on androgen hormone level in women with acne vulgaris

Protocol summary

Summary

Aim of the study is evaluation the effect of Isotretinoin on androgen level in women with Acne Vulgaris. Inclusion criteria: 18-30 years old women with moderate to severe acne vulgaris. Exclusion criteria: pregnancy; hypersensitivity to parabens; poly cystic ovarian disease; recent history of mood or depressive disorders; thyroid disease; pituitary disease and use of Finasteride; retinoids or hormonal contraception within three months of enrollment. Sample size: 36 women who involved acne vulgaris. Intervention: 20 mg isotretinoine (Roaccutane) daily for a period of three months. Outcome study: comparison between androgenic hormones levels dehydroepiandrosterone (DHEA), 17-hydroxyprogestrone, testosterone, free testosterone, dihydrotestosterone (DHT), luteinizing hormone (LH), follicle stimulating hormone (FSH) and prolactin before and after the intervention.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017052725407N2**
Registration date: **2017-06-07, 1396/03/17**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2017-06-07, 1396/03/17

Registrant information

Name

Amir Feily

Name of organization / entity

Skin and Stem Cell Research Center, Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 715234665

Email address

dr.feily@jums.ac.ir

Recruitment status

Recruitment complete

Funding source

Jahrom University of Medical Sciences

Expected recruitment start date

2014-02-17, 1392/11/28

Expected recruitment end date

2015-11-18, 1394/08/27

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation the effect of isotretinoin on androgen hormone level in women with acne vulgaris

Public title

The effect of isotretinoin in the treatment of acne

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: 18-30 years old women with moderate to severe acne vulgaris. Exclusion criteria: pregnancy; hypersensitivity to parabens; poly cystic ovarian disease; recent history of mood or depressive disorders; thyroid disease; pituitary disease and use of Finasteride; retinoids or hormonal contraception within three months of enrollment.

Age

From **18 years** old to **30 years** old

Gender

Female

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **36**
Randomization (investigator's opinion)
N/A
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Single
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Jahrom University of Medical Sciences
Street address
Jahrom University of Medical Sciences, Motahari street
City
Jahrom
Postal code
Approval date
2014-02-26, 1392/12/07
Ethics committee reference number
IR.JUMS.REC.1392.063

Health conditions studied

1

Description of health condition studied
Acne
ICD-10 code
L70.0
ICD-10 code description
Acne Vulgaris

Primary outcomes

1

Description
Dihydrotestosterone
Timepoint
Before and after the intervention
Method of measurement
ng/ml

2

Description
17-hydroxyprogestrone
Timepoint
Before and after the intervention
Method of measurement
ng/ml

3

Description
Testosterone
Timepoint
Before and after the intervention
Method of measurement
ng/ml

4

Description
Dehydroepiandrosterone
Timepoint
Before and after the intervention
Method of measurement
ng/ml

5

Description
Free testosterone
Timepoint
Before and after the intervention
Method of measurement
ng/ml

6

Description
Luteinizing hormone
Timepoint
Before and after the intervention
Method of measurement
ng/ml

7

Description
Follicle stimulating hormone
Timepoint
Before and after the intervention
Method of measurement
ng/ml

8

Description
Prolactin
Timepoint
Before and after the intervention
Method of measurement
ng/ml

Secondary outcomes

empty

Intervention groups

1

Description
Orally tablet of 20 mg isotretinoine (Roaccutane)daily for a period of three months
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Hair and Skin clinic
Full name of responsible person
Dr. Amir Feily
Street address
Moalem Blvd.
City
Jahrom

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Jahrom University of Medical Sciences
Full name of responsible person
Dr. Kavous Solhju, Vice chancellor for research
Street address
Jahrom University of Medical Sciences, Motahari street
City
Jahrom
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Jahrom 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
Name of organization / entity
Jahrom University of Medical Sciences
Full name of responsible person
Dr. Amir Feily
Position
Dermatologist
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Person responsible for updating data

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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