

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Sep 2026

Effects of oral isotertinoin on folic acid, homocysteine and biochemical and hematological markers in acne vulgaris patients

Protocol summary

Summary

Introduction: The aim of the present study was the evaluation of serum level of lipids and liver enzymes markers, folic acid, homocysteine and hematological markers in patients with acne vulgaris undergoing isotertinoin treatment. Methods: Forty-four patients, with severe acne or moderate acne who were resistant to conventional treatment were supplemented with 0.5 mg/kg/day of oral isotertinoin for 120 days. We would exclud diabetic patients, coronary heart disease, metabolic disorders and etc. The serum levels of cholesterol, triglyceride, liver enzymes markers, folic acid, homocysteine, urea and creatinine measured at the baseline and at the end of the treatment period. Then white blood cell (WBC), red blood cell (RBC) and platelets were counted; also the level of hemoglobin and hematocrite were measured.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2012103011316N1**

Registration date: **2013-01-08, 1391/10/19**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2013-01-08, 1391/10/19

Registrant information

Name

Hassan Ahmadvand

Name of organization / entity

Department of Biochemistry

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Recruitment status

Recruitment complete

Funding source

Lorestan University of Medical Sciences

Expected recruitment start date

2012-10-31, 1391/08/10

Expected recruitment end date

2013-02-28, 1391/12/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of oral isotertinoin on folic acid, homocysteine and biochemical and hematological markers in acne vulgaris patients

Public title

Effects of oral isotertinoin on folic acid, homocysteine and biochemical and hematological markers in acne vulgaris patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criterion: patients with acne vulgaris on general diet. Exclusion Criteria: patients use others drugs; diabete mellitus; coronary heart disease; metabolic Disease and other serious diseases.

Age

From **17 years** old to **40 years** old

Gender

Both

Phase

1

Groups that have been masked

No information

Sample size

Target sample size: 44

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

Lorestan University of Medical Sciences-research center

Street address

1Department of Clinical Biochemistry, School of Medicine, Lorestan University of Medical Sciences, Khorramabad, Iran

City

Khorramabad

Postal code

Approval date

2012-01-31, 1390/11/11

Ethics committee reference number

1275

Health conditions studied

1

Description of health condition studied

acne vulgaris

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Folic acid

Timepoint

at the baseline and end of the treatment period (120 day)

Method of measurement

by immunoassay method using commercial randox kits

2

Description

Homosysteine

Timepoint

at the baseline and end of the treatment period (120 day)

Method of measurement

by immunoassay method using commercial Randox kits

Secondary outcomes

1

Description

Lipid profile

Timepoint

at the baseline and end of the treatment period (120 day)

Method of measurement

by autoanalyzer using commercial pars azemon kits

2

Description

Gama glutamiltransferase

Timepoint

at the baseline and end of the treatment period (120 day)

Method of measurement

by autoanalyzer using commercial pars azemon kits

3

Description

Alanin trans aminase

Timepoint

at the baseline and end of the treatment period (120 day)

Method of measurement

by autoanalyzer using commercial pars azemon kits

4

Description

Aspartat trans aminase

Timepoint

at the baseline and end of the treatment period (120 day)

Method of measurement

by autoanalyzer using commercial pars azemon kits

Intervention groups

1

Description

Intervention Treatment of patient would supplement with 0.5 mg/kg/day of oral isotretinoin for 120 days

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Hospital of Shohadaie Ashaier

Full name of responsible person

Street address

City

Khorramabad

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Lorestan University of Medical Sciences

Full name of responsible person

Mohammad Hassan Kayedi

Street address

School of Medicine, Lorestan University of Medical Sciences, Khorramabad, Iran

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Khorramabad

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Lorestan 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

Lorestan University of Medical Sciences

Full name of responsible person

Hassan Ahmadvand

Position

associated professor

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