

Clinical Trial Protocol

Iranian Registry of Clinical Trials

24 Jul 2026

Compare of the efficacy of low-dose and conventional dose of oral Isotretinoin in the treatment of moderate to severe acne vulgaris.

Protocol summary

Summary

Objectives: To comparison of the efficacy of low-dose and conventional dose of oral Isotretinoin in the treatment of moderate to severe acne vulgaris. Design: Randomized, single blind, clinical trial. Patients were blinded to the intervention group. Setting and Conduct: 60 patients that involved in moderate to severe acne vulgaris. They are placed in 2 groups. Per group has 30 patients. group 1 treated with 0.5 mg per kg daily of oral isotrtinoin for 6 months and group 2 treated with 0.25 mg per kg daily of oral isotrtinoin for 6 months. Outcome measures will be assessed by the use of global acne grading system at baseline and 6 and 12 months later. Major Inclusion and Exclusion criteria: Inclusion criteria: absence of hypersensitivity to retinoid; absence of pregnancy or plan of pregnancy; no history of hormonal abnormality exclusion criteria: impassible to follow up; use of other treatment Intervention: One group treated with low dose of oral isotretinoin and other group treated with traditional dose of oral isotretinoin. Main Outcome Measures: Improvement in skin lesions of acne vulgaris assessed by global acne grading system.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015061722780N1**

Registration date: **2016-05-29, 1395/03/09**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-05-29, 1395/03/09

Registrant information

Name

Nasrin Motamedi fard

Name of organization / entity

Isfahan University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Isfahan University of Medical Sciences + Patients + Investigator

Expected recruitment start date

2014-09-06, 1393/06/15

Expected recruitment end date

2016-03-05, 1394/12/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Compare of the efficacy of low-dose and conventional dose of oral Isotretinoin in the treatment of moderate to severe acne vulgaris.

Public title

Efficacy of oral low-dose Isotretinoin in the treatment of acne vulgaris

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Absence of hypersensitivity to Retinoid; Absence of pregnancy or plan of pregnancy; no history of hormonal abnormality exclusion criteria: impossible to follow up; use of another treatment

Age

From **15 years** old to **70 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Single blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features

random allocation was by blocking method.

Secondary Ids

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Isfahan University of Medical Sciences

Street address

Deputy of research of Isfahan University of Medical Sciences, Hezar jerib Avenue, Isfahan.

City

Isfahan

Postal code**Approval date**

2014-11-06, 1393/08/15

Ethics committee reference number

393894

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**

Quantity of skin lesions of acne vulgaris

Timepoint

At first and six months after initiation of treatment and six months after cessation of treatment

Method of measurement

Computation of lesions and utilization of global acne grading system

Secondary outcomes**1****Description**

Increase of liver enzymes and increase of serum lipid profile

Timepoint

At first and one and two and four and six months after initiation of treatment

Method of measurement

Transmission of blood sample to medical laboratory

Intervention groups**1****Description**

Prescription of low dose of oral isotretinoin in intervention group (0.25 mg/kg/day) six months

Category

Treatment - Drugs

2**Description**

prescription of traditional dose of oral isotretinoin (0.5 mg/kg/day) six months

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

AL Zahra Hospital and Sedigheh tahere center

Full name of responsible person

Dr Nasrin Motamedi Fard

Street address

Department of Dermatology, Al Zahra Hospital, Isfahan

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Sponsors / Funding sources**1****Sponsor**

Name of organization / entity

Vice chancellor for research of Isfahan University of Medical Sciences

Full name of responsible person

Dr. Mehdi Nematbakhsh

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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

Vice chancellor for research of Isfahan 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**

Isfahan University Of Medical Science

Full name of responsible person

Dr Nasrin Motamedi Fard

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

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Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code
empty

Data Dictionary
empty