

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

Comparison of the effect of oral isotretinoin with isotretinoin and des loratadine in the treatment of moderate and severe acne vulgaris

Protocol summary

Study aim

Comparison of the effect of oral isotretinoin with isotretinoin and des loratadine in the treatment of moderate and severe acne vulgaris

Design

A clinical trial with a control group, parallel groups, single-blind, phase 3 on 60 patients. Non-random, assigning individuals to groups using the file numbers (even or odd).

Settings and conduct

Samples will be selected from patients referred to Isfahan University of Medical Sciences. Patients are examined by a physician before receiving the drug and at 8, 16, and 24 weeks and are evaluated by the Global Acne Grading System. and Patients report side effects of isotretinoin. Lab tests will be requested at the beginning and 2 months of treatment. Photographs will be taken at the beginning and after 24 weeks and will be evaluated by two dermatologists who are not performing the project.

Participants/Inclusion and exclusion criteria

Inclusion criteria: patients with moderate to severe acne, patients aged at least 15 years. Exclusion criteria: Pregnant and lactating women, liver and kidney disorders; hyperlipidemia; a history of retinoid allergies; taking oral medication for acne for the past 2 months.

Intervention groups

All patients receive standard acne treatment, which includes isotretinoin 20 mg capsules daily, and one group, in addition to the above protocol, is treated with 5 mg des loratadine daily.

Main outcome variables

GAGS system score, number of inflammatory and non-inflammatory lesions, evaluation of side effects of isotretinoin

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20211010052723N1**

Registration date: **2021-11-18, 1400/08/27**

Registration timing: **prospective**

Last update: **2021-11-18, 1400/08/27**

Update count: **0**

Registration date

2021-11-18, 1400/08/27

Registrant information

Name

Mahya Abedini

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 7745 1109

Email address

aabedini.ma@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-11-21, 1400/08/30

Expected recruitment end date

2022-09-21, 1401/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of oral isotretinoin with isotretinoin and des loratadine in the treatment of moderate and severe acne vulgaris

Public title

Evaluation of the effect of desloratadine in the treatment of acne

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Patient consent to participate in the study Age over 15 years No history of allergy to retinoid compounds Do not take oral medications to treat acne for the past 2 months

Exclusion criteria:

liver or kidney disease and dyslipidemia pregnancy or desire to get pregnant breastfeeding

Age

From 15 years old

Gender

Both

Phase

3

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: 60

Randomization (investigator's opinion)

Not randomized

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

Single blinded

Blinding description

The photograph will be evaluated by two non-executors dermatologists.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics Committee of Isfahan University of Medical Sciences

Street address

No. 58, Shania Madanian Ave, Behdari Lashgar Street, A rtesh Blvd., Isfahan

City

Isfahan

Province

Isfahan

Postal code

8174755636

Approval date

2021-10-03, 1400/07/11

Ethics committee reference number

IR.MUI.MED.REC.1400.548

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**

Acne Score with GAGS (Global Acne Grading System)

Timepoint

Evaluation of acne lesions before receiving the drug and at weeks 8, 16 and 24

Method of measurement

In the Global Acne Grading System 19 to 30 are considered moderate, 31-38 severe and above 38 very severe.

2**Description**

Evaluation of the side effects of isotretinoin [dry skin, lips (Mild, moderate and severe), dry eyes, nosebleeds, and hair loss].

Timepoint

at weeks 8, 16 and 24

Method of measurement

Asking the patients

Secondary outcomes

empty

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

Intervention group: Patients undergoing standard treatment for moderate to severe acne, including isotretinoin capsule (PHARMATHEN ACNOTREN) 20mg daily and clindamycin 1% solution (manufactured by Pak Drug factory) daily Patients with severe acne are also given azithromycin 250 mg by FATAK CHEMIE PARS daily for one month and receive 5 mg of desloratadine (neotadine produced by Abaidi factory) daily. Patients with severe and moderate disease severity are divided into two equal groups. Patients are treated for six months.

Category

Treatment - Drugs

2

Description

Control group: Patients undergoing standard treatment for moderate to severe acne, including isotretinoin capsule (PHARMATHEN ACNOTREN) 20mg daily and clindamycin 1% solution (manufactured by Pak Drug factory) daily. Patients with severe acne are also given azithromycin 250 mg by FATAK CHEMIE PARS daily for one month. Patients with severe and moderate disease severity are divided into two equal groups. Patients are treated for six months.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Alzahra hospital

Full name of responsible person

Mahya Abedini

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2

Recruitment center

Name of recruitment center

SedigheTahere hospital

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Dr. Shaghayegh Haghjoo Javanmard

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Vice President for Research and Technology, Building No. 4, University of Esfahan, Hezar jerib St

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research@mui.ac.ir

Web page address

<http://research.mui.ac.ir>

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Esfahan University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Mahya Abedini

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Dermatology

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

At the end of the study, study protocol, statistical analysis and clinical study report, the informed consent form, the codes used in the data analysis and the data dictionary can be shared with other researchers.

When the data will become available and for how long

Access period starts one month after the results are published

To whom data/document is available

Data will be available to researchers working in academic and scientific centers

Under which criteria data/document could be used

Researchers can use the findings and data of this study in their research by submitting a document that proves their employment in scientific and academic centers.

From where data/document is obtainable

Researchers can receive study data via sending an E-mail to researcher E-mail: Aabedini.ma@gmail.com phone number: 09128021807 Dr Mahya Abedini address: , Behdari lashgar Ave, Artesh Blv, Isfahan, Iran

What processes are involved for a request to access data/document

Researchers can send an email to the address to indicate the type of data they need, and after reviewing their request, the information will be sent to them via email.

Comments