

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Jun 2026

Comparative of the effect of oral isotretinoin and desloratadine with oral isotretinoin in the treatment of moderate to severe acne vulgaris patients

Protocol summary

Study aim

Determining and comparing the effect of using oral isotretinoin and desloratadine with oral isotretinoin in the treatment of moderate to severe acne vulgaris.

Design

A clinical trial with a control group, with parallel groups, double-blind, randomized, phase 3, on 70 patients.

Settings and conduct

The current research is a randomized clinical trial. whose statistical population consists of patients diagnosed with acne vulgaris who referred to the skin clinic of Sinai Hospital in Hamedan in the years 1401 to 1402. Patients who met the conditions for entering the study will be interviewed after completing the consent form and all patient information such as age, gender, acne severity score, number of lesions and type of skin lesions will be recorded in the checklist. Patients will be randomly classified into two treatment groups in such a way that in terms of disease severity, age and gender are equally distributed in both groups. In order to avoid bias in this study, the researcher and the patient do not know the type of drug assigned and the study is conducted in a double-blind manner.

Participants/Inclusion and exclusion criteria

Criteria for entering the study: People with moderate to severe acne Exclusion criteria: Age less than 18 years, pregnant and lactating women or women who plan to become pregnant in the near future (due to the teratogenicity of isotretinoin), people with systemic diseases

Intervention groups

the first group (A): treatment with isotretinoin capsule 20 mg once daily after lunch and desloratadine 10 mg tablet at night before going to sleep for 12 weeks. The second group (B): treatment with isotretinoin capsules 20 mg daily after meals and placebo tablets at night before sleep for 12 weeks.

Main outcome variables

Number of acne lesions after treatment

General information

Reason for update

Due to the shortage of Loratadine drug in the pharmaceutical market of the country at beginning of the trial, with the coordination of the Faculty of Medicine and the Ethics Committee, we changed the drug to Desloratadine, which was available , therefore each field that contains the word Loratadine to Desloratadine will be updated.

Acronym

IRCT registration information

IRCT registration number: **IRCT20220705055374N1**

Registration date: **2022-07-11, 1401/04/20**

Registration timing: **prospective**

Last update: **2023-12-09, 1402/09/18**

Update count: **1**

Registration date

2022-07-11, 1401/04/20

Registrant information

Name

Forough Eftekhari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 937 054 4655

Email address

forough.eftekhari8@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-08-23, 1401/06/01

Expected recruitment end date

2023-08-23, 1402/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative of the effect of oral isotretinoin and desloratadine with oral isotretinoin in the treatment of moderate to severe acne vulgaris patients

Public title

Comparative of the effect of oral isotretinoin and desloratadine with oral isotretinoin in the treatment of moderate to severe acne vulgaris patients

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Patient with moderate to severe acne

Exclusion criteria:

Age<18 years Pregnant and lactating female Systemic disease Concurrent use of other acne therapies Other dermatological condition requiring interfering treatment

AgeFrom **18 years** old**Gender**

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample sizeTarget sample size: **70****Randomization (investigator's opinion)**

Randomized

Randomization description

Random allocation rule: The number of samples allocated to each of the studied groups is equal, so that the intervention group includes 35 people and the control group also includes 35 people. 35 balls for the intervention group and 35 balls for the control group are drawn in a container. and then the balls are randomly removed from the container without replacement and the created sequence is recorded.

Blinding (investigator's opinion)

Double blinded

Blinding description

Desloratadine tablets and placebo tablets will be prepared in the same sealed envelopes so that neither the researcher nor the patient will know the type of drug.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics committee of Hamedan University of Medical Sciences

Street address

Khawaja Rashid Crossroad - Beginning of Ayatollah Kashani Blvd - University of Medical Sciences and Health Services of Hamedan Province

City

Hamedan

Province

Hamadan

Postal code

۶۵۱۷۸۳۸۷۳۶

Approval date

2022-06-27, 1401/04/06

Ethics committee reference number

IR.UMSHA.REC.1401.319

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**

Number of acne lesions after treatment

Timepoint

At baseline and at weeks 4, 8 and 12 after treatment

Method of measurement

Observe and record in the checklist

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Treatment with isotretinoin capsule 20 mg once daily after lunch and desloratadine 10 mg tablet at night before sleep for 12 weeks.

Category

Treatment - Drugs

2

Description

Control group: Treatment with isotretinoin capsules 20 mg daily after meals and placebo tablets at night before sleep for 12 weeks.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Sina hospital

Full name of responsible person

Forough Eftekhari

Street address

Hamadan University of Medical Sciences, Shahid Fahmideh Blvd., Pajoohesh square, Hamadan University of Medical Sciences

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Reza Shokoohi

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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

Hamedan 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

Hamedan University of Medical Sciences

Full name of responsible person

Forough Eftekhari

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Dermatology

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Bahareh Ebrahimi

Position

Assistant Professor

Latest degree

Specialist

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Dermatology

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Person responsible for updating data**Contact****Name of organization / entity**

Hamedan University of Medical Sciences

Full name of responsible person

Forough Eftekhari

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Others

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No.78 , Rahemi Ave Bahmani Str

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

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available