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
Age
From **18 years** old
Gender
Both

Phase
3
Groups that have been masked

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

Sample size
Target 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 squareedan 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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Asistant Professor
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Specialist
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Dermatology

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Person responsible for updating data

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Resident
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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