Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 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)

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+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
Isfehan
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
Mahya Abedini

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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

Street address
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 scientific inquiries

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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