Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Evaluating the efficacy of Metformin with Isotretinoin in the treatment of patient with acne or delayed acne

Protocol summary

Study aim
The aim of this study was to compare the treatment of acne with Metformin compared with Isotretinoin.

Design
In this clinical trial study, 70 patients with acne who are referred to Rasoul- E Akram hospital are selected. Participants were randomly divided into two control and intervention groups. Outcome assessor and data analyzer has been blinded

Settings and conduct
This study will be carried out at Rasuol-E Akram Hospital of Iran University of Medical Sciences with the aim of acne treatment. Outcome assessor and data analyzer will be blinded of the type of intervention prescribed for each individual.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Start acne from adolescence and continue acne until the age of 25, start acne from adolescence and continue after 25 years, start acne after 25 years. Exclusion criteria: History of taking Metformin or Isotretinoin and history of chronic diseases of kidney, liver or heart

Intervention groups
The intervention group will take Metformin 500 mg twice daily for 6 months and the control group will take oral Isotretinoin 20 mg every other day for 6 months.

Main outcome variables
Investigating the changes of acne severity is the main consequences of the study.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20140624018210N8**
Registration date: **2018-10-21, 1397/07/29**
Registration timing: **registered_while_recruiting**
Last update: **2018-10-21, 1397/07/29**
Update count: **0**

Registration date
2018-10-21, 1397/07/29

Registrant information

Name
Elham Behrangi

Name of organization / entity
Iran University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-05-04, 1397/02/14

Expected recruitment end date
2019-04-03, 1398/01/14

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluating the efficacy of Metformin with Isotretinoin in the treatment of patient with acne or delayed acne

Public title
Evaluating the efficacy of Metformin with Isotretinoin in the treatment of acne

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Start acne from adolescence and continue acne until the age of 25 Start acne from adolescence and continue after 25 years Start acne after 25 years
Exclusion criteria:
History of taking Metformin or Isotretinoin History of chronic diseases of kidney, liver or heart

Age
From **25 years** old to **50 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **70**

Randomization (investigator's opinion)
Randomized

Randomization description
In this study, block randomization method is used. This method increases the probability that each arm will contain an equal number of individuals by sequencing participant assignments by each block.The randomization unit is individual and randomization's tool is a statistical software.

Blinding (investigator's opinion)
Double blinded

Blinding description
In this study, the outcome assessor and participants have been blinded. The outcome assessor is people who are responsible for gathering data and outcome variables and does not know which participant received which drug.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Iran University of Medical Siences

Street address
Iran University of Medical Siences, Shahid Hemmat highway

City
Tehran

Province
Tehran

Postal code
1449614535

Approval date
2018-09-12, 1397/06/21

Ethics committee reference number
IR.IUMS.FMD.REC.1397.048

Health conditions studied

1

Description of health condition studied
Acne

ICD-10 code
L70

ICD-10 code description
Acne

Primary outcomes

1

Description
Changes of acne severity

Timepoint
1, 3 and 6 months after intervention

Method of measurement
Clinical examination

Secondary outcomes

1

Description
Fasting blood sugar

Timepoint
Before starting the intervention and 6 months after the intervention

Method of measurement
Blood test

2

Description
Cholesterol

Timepoint
Before starting the intervention and 6 months after the intervention

Method of measurement
Blood test

3

Description
Triglyceride

Timepoint
Before starting the intervention and 6 months after the intervention

Method of measurement
Blood test

Intervention groups

1

Description
Intervention group: Metformin with a dose of 500 mg twice a day for 6 months will be taken along with other prescribed medicines.
Category
Treatment - Drugs

2

Description
Control group: Oral isotretinoin will be taken a dose of 20 mg twice a day for 6 months along with other prescribed medicines.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Rasoul- E Akram Hospital
Full name of responsible person
Somayeh Sadeghi
Street address
Rasoul- E Akram Hospital, Niayesh St, Sattarkhan Ave
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
Iran 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
Iran University of Medical Sciences
Full name of responsible person
Elham Behrangi
Position
Assistant Professor
Latest degree
Specialist
Other areas of specialty/work
Dermatology
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Person responsible for updating data

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Full name of responsible person

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Position

Dermatology resident

Latest degree

Medical doctor

Other areas of specialty/work

Dermatology

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is 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

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

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

Data Dictionary

Not applicable

Title and more details about the data/document

Findings of the study, demographic data of participants in the study, in addition to descriptive and analytical analysis of variables

When the data will become available and for how long

Availability 6 months after the end of study

To whom data/document is available

Dermatology

Under which criteria data/document could be used

In the case of comparison with other similar trials or treatment

From where data/document is obtainable

Iran University of Medical Sciences

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

By referring to the central library of Iran University of Medical Sciences can access to the text of the final report or article.

Comments