

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 May 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 Rasoul-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

Country

Iran (Islamic Republic of)

Phone

+98 21 6650 2040

Email address

behrangi.e@iums.ac.ir

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 Sciences

Street address

Iran University of Medical Sciences, 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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asomayeh1394@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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Malakouti.k@iums.ac.ir

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 scientific 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

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

Somayeh Sadeghi

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