

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Jul 2026

Evaluation of the effectiveness of Metformin in comparison with Doxycycline in treatment of patients with Acne Vulgaris skin disease.

Protocol summary

Study aim

Comparing the effect of Doxycycline versus Metformin and in treatment of moderate acne patients.

Design

This study is a phase 3, randomized, double blinded clinical trial study. 40 patients will be selected from the patients of Shiraz Shahid Faghihi Hospital dermatology office. sample size will be determined by NCSS software, power: 90% , p-value: 5% and by using similar previous study. the participants will be divided into 2 parallel groups, intervention and control groups, by using sealed envelope online Random allocation.

Settings and conduct

Doxycycline and Metformin will give to the patients according to the block randomization table monthly for 2 months. The clinical evaluator of the study will not know which patients received any of the drugs mentioned in the study. This study lacks a placebo and the effects of the two drugs are compared.

Participants/Inclusion and exclusion criteria

16-40 years old patients with moderate acne or acne that needs systemic antibiotic are included in the study. they should not have been treated with systemic medications since 1 month ago and should not have been treated with topical therapy since 2 weeks ago. the patients with history of hypersensitivity to the mentioned drugs and who can not come regularly for follow up are excluded. pregnant and breast feeding mothers and also patients with systemic diseases are excluded.

Intervention groups

The participants are divided into 2 groups. the control group will receive Doxycycline (Abidi company) 100mg per day 2 hours after meal. the intervention group will receive Metformin (Rasta Imen Daroo company) 500mg twice daily. both groups should use topical 5% benzoyl peroxide (Pangel) on the lesions every night.

Main outcome variables

Acne severity, response to treatment, the effect of acne on the patient's life

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201108049309N1**

Registration date: **2022-06-07, 1401/03/17**

Registration timing: **retrospective**

Last update: **2022-06-07, 1401/03/17**

Update count: **0**

Registration date

2022-06-07, 1401/03/17

Registrant information

Name

Nazafarin Yazdanpanah

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 3235 7434

Email address

nazafarin.yazdanpanah@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-12-14, 1399/09/24

Expected recruitment end date

2021-02-12, 1399/11/24

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effectiveness of Metformin in comparison with Doxycycline in treatment of patients with Acne Vulgaris skin disease.

Public title

Effect of Metformin in Acne Vulgaris

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

16-40 years old patients with moderate acne . They should not have been treated with systemic medications since 1 month ago. They should not have been treated with topical therapy since 2 weeks ago.

Exclusion criteria:

The patients with a history of hypersensitivity to metformin and doxycycline. . Patients with systemic diseases are excluded. The patients with systemic disease The pregnant and lactating women

Age

From **16 years** old to **40 years** old

Gender

Both

Phase

3

Groups that have been masked

- Investigator

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Metformin and Doxycycline will be put in alike boxes and by using sealed envelope online system block randomization will be done and the code of block randomization will be put on the boxes. drugs will be given to the participants monthly and the codes will not be clarified until the end of research (allocation concealment)

Blinding (investigator's opinion)

Single blinded

Blinding description

Due to the different forms of drugs, patients and clinical caregivers who deliver drugs to patients are not blind. But the clinical assessor blind to how patients intervene

Placebo

Not used

Assignment

Parallel

Other design features

All details and explanation are written in specific part.

Secondary Ids

empty

Ethics committees

1

Ethics committee**Name of ethics committee**

Ethics Committee of Shiraz University of Medical Sciences

Street address

Shiraz, Zand Ave, medical university, ethics committee

City

Shiraz

Province

Fars

Postal code

7134845794

Approval date

2020-12-12, 1399/09/22

Ethics committee reference number

IR.SUMS.MED.REC.1399.459

Health conditions studied

1

Description of health condition studied

Acne

ICD-10 code

L70.9

ICD-10 code description

Acne, unspecified

Primary outcomes

1

Description

acne severity

Timepoint

before treatment and 1,2 months after treatment

Method of measurement

Global acne grading system, burke and cunliffe and counting total lesion count

Secondary outcomes

1

Description

response to treatment

Timepoint

at the onset and 2 months after treatment

Method of measurement

asking patient himself

2

Description

effect of acne on patient life

Timepoint

before treatment and 2 months after treatment

Method of measurement

Cardiff Acne disability index method

Intervention groups

1

Description

Intervention group: Intervention group: Apometformin 500 mg twice daily+ topical benzoyl peroxide 5% (pangel) on the lesions every other night for 2 months

Category

Treatment - Drugs

2

Description

Control group: Doxycycline (Hakim company) 100 mg daily for 2 months + benzoyl proxide 5%gel(pangel) every other night on acne lesions ; the Intervention group: Metformin (Abidi Company) 500mg daily for 2 months +benzoyl proxide 5%gel(pangel) every other night on acne lesions

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Molecular dermatology Research center, Shiraz University of Medical sciences

Full name of responsible person

Nazafarin Yazdanpanah

Street address

Shiraz, Zand street, Shahid faghihi hospital, floor 3, Dermatology Department

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Dr. Younes Ghasemi

Street address

Shiraz, zand street, shiraz university of medical sciences, 7th floor, vice chancellor of research

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Phone

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Email

vcrdep@suma.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Shiraz 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

Shiraz University of Medical Sciences

Full name of responsible person

Nazafarin Yazdanpanah

Position

Dermatology Resident

Latest degree

Medical doctor

Other areas of specialty/work

Dermatology

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Shiraz, Zand street, Shahid faghihi hospital, floor 3, Dermatology Department

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Email

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

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Person responsible for updating data

Contact

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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

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

Demographic data and the result of the clinical trial

When the data will become available and for how long

One year later

To whom data/document is available

Researchers

Under which criteria data/document could be used

After the publication of the extracted article of the
clinical

From where data/document is obtainable

Sending Email to the researchers

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

Sending the request via the email

Comments