

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Association of response to doxycycline and Azithromycin antibiotics therapy with Angiotensin converting enzyme polymorphism in patients with moderate acne vulgaris

Protocol summary

Study aim

Determining the relationship between response to doxycycline and azithromycin antibiotic treatment with angiotensin-converting enzyme (ACE) gene polymorphism in patients with moderate acne vulgaris referred to Gonabad skin clinics in 2023

Design

Patients with moderate acne will be divided into two groups of 27 people, one group will receive doxycycline 100 mg daily along with topical treatment (benzoyl peroxide and tretinoin) and the other group will receive azithromycin 250 mg every other day along with topical treatment (benzoyl peroxide and tretinoin). Clinical trial without control group, with parallel groups, without blind strain, block randomization, and data will be analyzed after collection with statistical software SPSS version 22.

Settings and conduct

After obtaining consent from the patients and dividing them into two groups, one group will receive doxycycline and the other group will receive azithromycin, and then we will investigate the polymorphism.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1. Acne vulgaris with moderate severity according to the MAS SCORE classification system 2. Suffering from acne vulgaris with moderate severity according to Weishampain's classification system 3. Age over 12 years

Intervention groups

one group will receive doxycycline 100 mg daily along with topical treatment (benzoyl peroxide and tretinoin) and the other group will receive azithromycin 250 mg every other day along with topical treatment (benzoyl peroxide and tretinoin).

Main outcome variables

angiotensin converting enzyme gene polymorphism; Age; gender; treatment; rate of response to treatment; recovery from the doctor's point of view; the level of

patient satisfaction; duration of acne; Family history of acne

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230305057628N1**

Registration date: **2023-03-14, 1401/12/23**

Registration timing: **registered_while_recruiting**

Last update: **2023-03-14, 1401/12/23**

Update count: **0**

Registration date

2023-03-14, 1401/12/23

Registrant information

Name

alireza tavakolizadeh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 5725 7039

Email address

alirezatavakolizadeh@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-03-11, 1401/12/20

Expected recruitment end date

2023-06-22, 1402/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty
Trial completion date
empty

Scientific title
Association of response to doxycycline and Azithromycin antibiotics therapy with Angiotensin converting enzyme polymorphism in patients with moderate acne vulgaris

Public title
Association of response to doxycycline and Azithromycin antibiotics therapy with Angiotensin converting enzyme polymorphism in patients with moderate acne vulgaris

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Acne vulgaris with moderate severity according to the MAS SCORE classification system Suffering from acne vulgaris with moderate severity according to Weishampain's classification system

Exclusion criteria:

Age
From **12 years** old

Gender
Both

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **54**

Randomization (investigator's opinion)
Randomized

Randomization description
Permuted block randomization, At first, the people who meet the criteria for entering the study will be selected based on the purpose after obtaining the consent to participate in the study, and then the people will be divided into two intervention groups in the form of block allocation.

Blinding (investigator's opinion)
Not blinded

Blinding description
Placebo

Not used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1
Ethics committee
Name of ethics committee
ethics committee of gonabad university of medical sciences

Street address
House number 30, Imam Ali 2 street, gonabad city
City
gonabad
Province
Razavi Khorasan
Postal code
9691998984

Approval date
2023-02-26, 1401/12/07
Ethics committee reference number
IR.GMU.REC.1401.182

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
Angiotensin converting enzyme gene polymorphism
Timepoint
After the end of the treatment period
Method of measurement
PCR and electrophoresis

2
Description
Response to treatment
Timepoint
Before starting the treatment, after the end of the treatment
Method of measurement
MAS score

Secondary outcomes

empty

Intervention groups

1
Description
Intervention group: At first, the patients are examined by a dermatologist and the severity of their acne is measured based on the Michelson acne score, and the patients are subjected to standard Photography. Next, the patients are divided into two groups. The first group receives doxycycline 100 mg daily along with topical treatment (benzoyl peroxide and tretinoin).
Category

Treatment - Drugs

2

Description

Intervention group: At first, the patients are examined by a dermatologist and the severity of their acne is measured based on the Michelson acne score, and the patients are subjected to standard Photography. Next, the patients are divided into two groups. The second group receives 250 mg of azithromycin every other day along with topical treatment (benzoyl peroxide and tretinoin).

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Bohloul hospital

Full name of responsible person

Hamideh mohammadzadeh

Street address

Bohloul hospital, Parastar Blvd, Gonabad city

City

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9691797852

Phone

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Email

Mohammadzadeh.hamideh@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Gonabad University of Medical Sciences

Full name of responsible person

Leila sadegh moghadam

Street address

Gonabad University of Medical Sciences, Dr mehdizadeh Blvd, Gonabad city

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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

Gonabad 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

Gonabad University of Medical Sciences

Full name of responsible person

hamide mohammadzadeh

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

Gonabad University of Medical Sciences

Full name of responsible person

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Position

Assistant Professor

Latest degree

Specialist

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Dermatology

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

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Position

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Latest degree

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Other areas of specialty/work

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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

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

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

All the data will be provided to the researchers without names and specifications.

When the data will become available and for how long

After completing the research project and publishing the article

To whom data/document is available

All researchers

Under which criteria data/document could be used

To conduct similar research, researchers can access the results of the project by referring to the research assistant of Gonabad University of Medical Sciences with a written consent letter from the research assistant.

From where data/document is obtainable

Research assistant of Gonabad University

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

Researchers can have access to the results of the project by referring to the vice president of research of Gonabad University of Medical Sciences with a written consent letter from the vice president of research.

Comments