Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 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

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Email address

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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
Bohlool hospital

Full name of responsible person
Hamideh mohammadzadeh

Street address
Bohlool hospital, Parastar Blvd, Gonabad city

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9691797852

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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

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Full name of responsible person
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Position
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Person responsible for updating data

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Full name of responsible person

Hamideh mahammas

Position

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Latest degree

Specialist

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

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