

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Association of response to doxycycline and Azithromycin antibiotics therapy and IL-4 gene (SR8179190) polymorphism in patients with moderate acne vulgaris

Protocol summary

Study aim

Determining the relationship between doxycycline and azithromycin antibiotic treatment and IL_4 gene polymorphism in patients with moderate acne vulgaris referred to skin clinics in Gonabad city in 2023-2024

Design

The trial with parallel groups, phase two will be conducted on 54 patients, dividing patients into study groups based on random allocation (block).

Settings and conduct

Patients with moderate acne who refer to Gonabad skin clinics are divided into two groups of 27 people and treatments are assigned, photography and determination of Michelson's acne score and patient satisfaction level before and after acne treatment will be done and after completion During the treatment period, 2 ml of blood will be taken from each person and polymorphisms will be checked. After checking the presence of mutation we will investigate the relationship between homozygous/heterozygous Burden and response to treatment

Participants/Inclusion and exclusion criteria

Entry criteria: suffering from acne vulgaris with moderate severity according to the classification system (MAS score); suffering from acne vulgaris with moderate severity according to the Weichamp classification system; age over 12 years old. Exit criteria: failure to complete the treatment process by the patient; occurrence of unusual complications during the treatment; patient's refusal to continue the treatment process.

Intervention groups

One group will receive doxycycline along with local treatment (benzoyl peroxide and tretinoin) and the other group will receive azithromycin along with local treatment (benzoyl peroxide and tretinoin).

Main outcome variables

Acne severity; recovery from the doctor's opinion; satisfaction level

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230305057631N1**

Registration date: **2023-05-24, 1402/03/03**

Registration timing: **registered_while_recruiting**

Last update: **2023-05-24, 1402/03/03**

Update count: **0**

Registration date

2023-05-24, 1402/03/03

Registrant information

Name

Younes Karami

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 81 3429 3933

Email address

1377younes@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-03-13, 1401/12/22

Expected recruitment end date

2023-08-21, 1402/05/30

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 and IL-4 gene (SR8179190) polymorphism in patients with moderate acne vulgaris

Public title
Association of response to doxycycline and Azithromycin antibiotics therapy and IL-4 gene (SR8179190) polymorphism in patients with moderate acne vulgaris

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Acne vulgaris with moderate severity according to the classification system (MAS score) Acne vulgaris with moderate severity according to vaishampayan classification system Age over 12 years
Exclusion criteria:
Failure to complete the treatment process by the patient
Occurrence of unusual complications during treatment
The patient's refusal to continue the treatment process

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
Block randomization, at first, the people who meet the criteria to enter the study will be selected to participate in the study based on their consent, and then the people will be divided into two intervention groups in the form of block allocation. In order to assign patients to two treatment groups, the Blocked Randomization method with blocks of four will be used. First, six possible states of blocks (BAAB, ABBA, BABA, BBAA, ABAB, AABB) are listed and a number from one to six is assigned to each block. Then, numbers between one and six are randomly selected using a table of random numbers, and then people are assigned to the azithromycin (A) and doxycycline (B) group based on the block corresponding to the selected number, and this work is done until completion. The sample size will continue.

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

Gonabad University of Medical Sciences

Street address

Gonabad University of Medical Sciences, near Asabi Road

City

Gonabad

Province

Razavi Khorasan

Postal code

9691793718

Approval date

2023-01-24, 1401/11/04

Ethics committee reference number

IR.GMU.REC.1401.138

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

Response to treatment

Timepoint

Before starting the treatment, after the end of the treatment

Method of measurement

MAS score

2

Description

Satisfaction level

Timepoint

Before starting the treatment, after the end of the treatment

Method of measurement

check list

3

Description

Recovery from the doctor's opinion

Timepoint

Before starting the treatment, after the end of the treatment

Method of measurement

Check list

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: At first, the patients were examined by a dermatologist and the severity of their acne was measured based on the Michelson acne score, and the patients were 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 were examined by a dermatologist and the severity of their acne was measured based on the Michelson acne score, and the patients were 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.

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Gonabad University of Medical Sciences

Full name of responsible person

Leila Sadegh Moghadam

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Gonabad University of Medical Sciences, Dr Mehdizadeh Blvd.

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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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Position

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Person responsible for updating data

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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