

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of the efficacy of Azithromycin and Doxycycline in cases of moderate intensity inflammatory papulopustular acne, a randomized clinical trial

Protocol summary

Study aim

Comparison of the efficacy of Azithromycin and Doxycycline in cases of moderate intensity inflammatory papulopustular acne

Design

This is a parallel randomized clinical trial that will perform on 140 patients with papulopustular acne. Randomization will perform with permuted blocked randomization using SPSS syntax. The block size will be 4. This study will enroll for 6 months.

Settings and conduct

This study will conduct as a clinical trial study with 140 patients who will refer to Imam Hossain Hospital of Shahroud. Patients must sign an informed consent form before entering the study. In this study; clinical caregiver and the analyzer will blind.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with moderate inflammatory papulopustular acne; Age range 15-50 years; and satisfaction with participation to the research. Exclusion criteria: previous burns or local scars; doing restorative skin care like laser; Severe hormonal disorders such as hypothyroidism; Chronic liver and kidney disease; Pregnancy and lactation.

Intervention groups

Patients entered into the study are divided into intervention and control groups. In the intervention group; treatment with Azithromycin plus tretinoin topical lotion 0.5% will be prescribed in the third month. In the control group; treatment with just ferrous sulfate tablet in the third month will be performed.

Main outcome variables

Acne healing speed

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20100102002954N16**

Registration date: **2019-09-15, 1398/06/24**

Registration timing: **registered_while_recruiting**

Last update: **2019-09-15, 1398/06/24**

Update count: **0**

Registration date

2019-09-15, 1398/06/24

Registrant information

Name

Mohammad Bagher Sohrabi

Name of organization / entity

Shahroud University of Medical Sciences and Health

Country

Iran (Islamic Republic of)

Phone

+98 23 3239 5054

Email address

mb.sohrabi@shmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-09-06, 1398/06/15

Expected recruitment end date

2019-12-06, 1398/09/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the efficacy of Azithromycin and Doxycycline in cases of moderate intensity inflammatory papulopustular acne, a randomized clinical trial

Public title

Comparison of the efficacy of Azithromycin and Doxycycline in treatment of acne

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with moderate inflammatory papulopustular acne, Age range 15-50 years, Satisfaction with the research.

Exclusion criteria:

Previous burns, Severe hormonal disorders such as hypothyroidism, Chronic liver and kidney disease, Pregnancy and lactation, doing restorative skin care like laser

Age

From **15 years** old to **50 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **140**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization was done using permuted block randomization method using blocked random allocation syntax in SPSS software. For calculation sample size, number of blocks and block size was determined. Block size was 4. Allocation concealment was done using closed opaque envelope.

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 Shahroud University of Medical Sciences

Street address

Shahroud University of Medical Sciences; 7 Tir squer, Shahroud

City

Shahroud

Province

Semnan

Postal code

3616647555

Approval date

2017-08-31, 1396/06/09

Ethics committee reference number

IR.SHMU.REC.1396.155

Health conditions studied

1

Description of health condition studied

Acne conglobata

ICD-10 code

L70.1

ICD-10 code description

Acne conglobata

Primary outcomes

1

Description

Acne healing speed

Timepoint

Once every two weeks

Method of measurement

Skin imaging and global response assessment

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Using Azithromycin tablet (Pars darou Company) in a single dose (250 mg/day) orally for three months in addition using topical Tertoin lotion 0.05% (Alborz company) twice a day (10 drops per 12 hours, locally) for three months.

Category

Treatment - Drugs

2

Description

Control group: Using of a Doxycycline capsule (Pars Darou company) twice a day orally (total 200 mg/ daily) in addition to topical Tertoin lotion 0.05% (Alborz company) twice a day (10 drops per 12 hours, locally) for three months.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Hossein Hospital of Shahroud

Full name of responsible person

Dr. Marjan Talebi

Street address

Imam Hossein Hospital., End Imam street., Shahroud , Iran

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Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahroud University of Medical Sciences

Full name of responsible person

Dr. Mohammad Hasan Emamian

Street address

Vice chancellor for research; Shahroud University medical Sciences ,7th Tir squar, Shahroud

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Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

No

Title of funding source

Vice chancellor for research; Shahroud University medical and 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**

Shahroud University of Medical Sciences

Full name of responsible person

Dr.Mohammad Bagher Sohrabi

Position

General practitioner

Latest degree

Medical doctor

Other areas of specialty/work

General Practitioner

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Person responsible for scientific inquiries

Contact**Name of organization / entity**

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Full name of responsible person

Dr. Marjan Talebi

Position

Dermatologist

Latest degree

Specialist

Other areas of specialty/work

Dermatology

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Person responsible for updating data

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Latest degree
Medical doctor
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Sharing plan

Deidentified Individual Participant Data Set (IPD)

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

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available