

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jul 2026

Comparing the efficacy of combination of doxycycline and montelukast versus doxycycline and placebo in the treatment of patients with moderate acne vulgaris referring to Shahid Faghihi hospital,1397-98

Protocol summary

Study aim

comparing the effect of combination of doxycycline and Montelukast with doxycycline and placebo in treatment of moderate acne

Design

this study is a phase 3, randomized, double blinded clinical trial study. 160 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 system block randomization.

Settings and conduct

placebo and Montelukast will be put in alike boxes and the randomized codes of block randomization will be put on each box. the codes will not be clarified until the end of study. the care giver and the investigator don't know the intervention and placebo groups. the patients will receive medications monthly for 3 months.

Participants/Inclusion and exclusion criteria

15-35 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.

Intervention groups

the participants are divided into 2 groups. the control group will receive combination of doxycycline (hakim company) 100 mg daily and placebo. the intervention group will receive doxycycline 100 mg daily and Montelukast (abidi company) 10 mg every night. both groups should use topical 5% benzoyl peroxide (pangel) on the lesions every other 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: **IRCT20191013045092N1**

Registration date: **2019-11-10, 1398/08/19**

Registration timing: **prospective**

Last update: **2019-11-10, 1398/08/19**

Update count: **0**

Registration date

2019-11-10, 1398/08/19

Registrant information

Name

Ladan Dastgheib

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 3231 9049

Email address

dastghl@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-11-11, 1398/08/20

Expected recruitment end date

2020-05-19, 1399/02/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the efficacy of combination of doxycycline and montelukast versus doxycycline and placebo in the treatment of patients with moderate acne vulgaris referring to Shahid Faghihi hospital,1397-98

Public title

Montelukast effect in acne treatment

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

patients with moderate acne or acne that needs systemic antibiotic for treatment patients have not been treated with systemic medications since 1 month ago and have not been treated with topical therapy since 2 weeks ago married women accept to have contraception during treatment

Exclusion criteria:

history of hypersensitivity to the mentioned drugs inability to come regularly for follow up disagree to continue treatment under 15 and above 35 years old patients with acne conglobata and acne fulminans receiving medications that have interaction with doxycycline and montelukast pregnancy and lactation using herbal therapy

Age

From **15 years** old to **35 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size

Target sample size: **160**

Randomization (investigator's opinion)

Randomized

Randomization description

montelukst and placebo 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)

Double blinded

Blinding description

informed consent will be taken from the participants and they don't know that they are receiving drug or placebo. the investigator and the care giver don't know the intervention and placebo group

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Shiraz University of Medical sciences

Street address

Shiraz, Zand street, medical university, ethics committee

City

Shiraz

Province

Fars

Postal code

7134845794

Approval date

2018-12-22, 1397/10/01

Ethics committee reference number

IR.SUMS.MED.REC.1397.385

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 1,2,3 months after treatment

Method of measurement

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

2**Description**

acne severity

Timepoint

before treatment and 3 months after treatment

Method of measurement

investigator global assessment score

Secondary outcomes

1

Description

response to treatment

Timepoint

before treatment and 3 months after treatment

Method of measurement

asking patients

2

Description

the effect of acne on the patient's life

Timepoint

before treatment and 3 months after treatment

Method of measurement

Cardiff Acne disability index

Intervention groups

1

Description

Intervention group: doxycycline (hakim company) 100 mg daily and Montelukast (abidi company) 10 mg every night + topical benzoyl peroxide 5% (pangel) on the lesions every other night for 3 months

Category

Treatment - Drugs

2

Description

Control group: doxycycline (hakim company) 100 mg daily + topical benzoyl peroxide 5% (pangel) on the lesions every other night + placebo for 3 months

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

Negin Fazelzadeh Haghighi

Street address

Department of Dermatology, floor 3, Shahid Faghihi
hospital, Zand avenue

City

Shiraz

Province

Fars

Postal code

7134846114

Phone

+98 71 3231 9049

Fax

+98 71 3231 9049

Email

neginfzd@yahoo.com

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

City

shiraz

Province

Fars

Postal code

7134814336

Phone

+98 71 3230 5410

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

Negin Fazelzadeh Haghighi

Position

dermatology resident

Latest degree

Medical doctor

Other areas of specialty/work

Dermatology

Street address

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

City
shiraz
Province
Fars
Postal code
7134846114
Phone
+98 71 3231 9049
Email
neginfzd@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Negin Fazelzadeh Haghighi
Position
dermatology resident
Latest degree
Medical doctor
Other areas of specialty/work
Dermatology
Street address
Shiraz, Zand street, Shahid faghihi hospital, floor 3,
Dermatology Department
City
shiraz
Province
Fars
Postal code
7134846114
Phone
+98 71 3231 9049
Email
neginfzd@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Negin Fazelzadeh Haghighi
Position
dermatology resident
Latest degree
Medical doctor
Other areas of specialty/work
Dermatology
Street address
Shiraz, Zand street, Shahid faghihi hospital, floor 3,
Dermatology Department
City
shiraz
Province
Fars
Postal code
7134846114
Phone
+98 71 3231 9049
Email
neginfzd@yahoo.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

there is no further information

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