

# 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

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##### Postal code

7134846114

##### Phone

+98 71 3231 9049

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+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

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##### 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

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## Person responsible for scientific inquiries

### Contact

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**Full name of responsible person**  
Negin Fazelzadeh Haghighi  
**Position**  
dermatology resident  
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Medical doctor  
**Other areas of specialty/work**  
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## Person responsible for updating data

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## 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