Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 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 recieving 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 concent will be taken from the participants and they don't know that they are recieving 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 comittee of Shiraz University of Medical sciences
Street address
Shiraz, Zand street, medical university, ethics comittee
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
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Department of Dermatology, floor 3, Shahid Faghihi hospital, Zand avenue
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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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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
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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