Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

A Comparative study of Doxycycline and Zinc Sulfate with Doxycycline in the treatment of acne vulgaris patients

Protocol summary

Study aim
A Comparative study of Doxycycline and Zinc Sulfate with Doxycycline in the treatment of acne vulgaris patients.

Design
This is a parallel randomized clinical trial that will perform on 140 patients with vulgaris acne. Randomization will perform with permuted blocked randomization using SPSS syntax. The block size will be 4. This study will enroll for 4 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 vulgaris 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 Doxycycline plus Zinc sulfat will be prescribed in the third month. In the control group; treatment with just Doxycycline capsula 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: **IRCT20100102002954N17**

Registration date: **2019-09-20, 1398/06/29**

Registration timing: **prospective**

Last update: **2019-09-20, 1398/06/29**

Update count: **0**

Registration date

2019-09-20, 1398/06/29

Registrant information

Name
Mohammad Bagher Sohrabi

Name of organization / entity
Shahroud University of Medical Ssciences and Health

Country
Iran (Islamic Republic of)

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+98 23 3239 5054

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mb.sohrabi@shmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-10-06, 1398/07/14

Expected recruitment end date

2020-02-03, 1398/11/14

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A Comparative study of Doxycycline and Zinc Sulfate with Doxycycline in the treatment of acne vulgaris patients

Public title

A Comparative study of Doxycycline and Zinc Sulfate with Doxycycline in the treatment of acne

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Patients with voulgaris 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
2018-03-05, 1396/12/14

Ethics committee reference number
IR.SHMU.REC.1396.160

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
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 Doxycycline capsula (Pars darou Company) in a double dose (200 mg/day) orally for three months in addition using Zinc sulfat tablet (Alborz company) daily (220mg/day) for three months.

Category
Treatment - Drugs

2

Description
Control group: Using Doxycycline capsula (Pars darou Company) in a double dose (200 mg/day) orally 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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Shahroud

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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

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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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Position

General Practitioner

Latest degree

Medical doctor

Other areas of specialty/work

General Practitioner

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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