

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jun 2026

Evaluation of the efficacy and safety of Doxycycline in combination with standard treatment in Covid-19 patients: a clinical trial

Protocol summary

Study aim

Evaluation of efficacy and safety of doxycycline in combination with standard treatment in patients with COVID-19

Design

Randomized controlled clinical trial, with intervention and control groups, without blinding, randomized, phase 3 per 60 patients, randomized by Permuted block randomization

Settings and conduct

This clinical trial will be performed on 60 patients aged 18 to 80 years in Shahid Sadoughi Hospital in Yazd. Patients are randomly divided into two intervention groups including doxycycline along with standard treatment and control group including standard treatment. At the beginning of the study, patients will be randomly assigned to one of two divided groups (30 people in each group). Patients in the intervention group receive doxycycline orally every 12 hours for 7 days along with standard treatment. Patients in the control group also receive placebo along with standard treatment. This study is a prospective randomized controlled clinical trial and will be performed on 60 patients who will be randomly assigned to two groups of 30 controls or intervention.

Participants/Inclusion and exclusion criteria

Minimum age 18 and maximum age 80 years, Signing up the informed consent form, Do not take doxycycline during the past 5 days, Patients suspected of COVID-19 based on clinical signs and manifestations of CT scan, Candidate for outpatient treatment: Patients hospitalized, Patients with hemodynamic instability, Patients with a history of allergic reaction or allergy to doxycycline, Second and third trimesters of pregnancy

Intervention groups

Intervention group: includes 30 patients who take 100 mg doxycycline capsules orally twice a day on the first to seventh days along with standard treatment. Control group: includes 30 patients who receive placebo along

with standard treatment.

Main outcome variables

Improve clinical symptoms including fever; Cough; Shortness of breath

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191211045691N2**

Registration date: **2020-11-02, 1399/08/12**

Registration timing: **retrospective**

Last update: **2020-11-02, 1399/08/12**

Update count: **0**

Registration date

2020-11-02, 1399/08/12

Registrant information

Name

Seyed Ruhollah Mousavinasab

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 3647 4332

Email address

mousavinasab@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-09-14, 1399/06/24

Expected recruitment end date

2020-11-02, 1399/08/12

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the efficacy and safety of Doxycycline in combination with standard treatment in Covid-19 patients: a clinical trial

Public title

Evaluation of the efficacy and safety of Doxycycline in combination with standard treatment in Covid-19 patients

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Minimum age 18 and maximum age 80 years Signing up the informed consent form Do not take doxycycline during the past 5 days Patients suspected of covid-19 based on clinical signs and manifestations of CT scan Candidate for outpatient treatment

Exclusion criteria:

Patients hospitalized Patients with hemodynamic instability Patients with a history of allergic reaction or allergy to doxycycline Second and third trimesters of pregnancy

Age

From **18 years** old to **80 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Block randomization (quadruple blocks) All possible blocks are arranged as follows: block 1: ABAB block 2: AABB block 3: ABBA block 4: BBAA block 5: BABA block 6: BAAB We need 15 blocks to select 60 people. We randomly select these blocks from the numbers 1 to 6. Using R software, we choose a random number between the numbers 1 to 6. For example, number 6 is chosen as the first block and number 2 as the fourth block. The people who enter the study are given B-A-A-BA- A-B-B, respectively. Finally, group A receives control intervention and group B receives treatment intervention

Blinding (investigator's opinion)

Double blinded

Blinding description

The researcher is unaware that the medicine given to the patient is the main medicine or placebo. The participant (patient) is also unaware that the medicine being given to them is the main medicine or placebo.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics Committee in Biomedical Research, School of Medicine, Shahid Sadoughi University of Medical S

Street address

دانشکده پزشکی ، دانشگاه علوم پزشکی و خدمات بهداشتی درمانی شهید صدوقی یزد ، بلوار شهدای گمنام ، بلوار استاد حسابی ، یزد ، ایران

City

yazd

Province

Yazd

Postal code

۸۹۱۶۹۷۸۴۷۷

Approval date

2020-09-13, 1399/06/23

Ethics committee reference number

IR.SSU.MEDICIN E.REC.1399.140

Health conditions studied**1****Description of health condition studied**

Evaluation of the efficacy and safety of doxycycline in combination with standard treatment in Covid-19 patients.

ICD-10 code

U07.1

ICD-10 code description

COVID-19, virus identified

Primary outcomes**1****Description**

Improve clinical symptoms including fever, shortness of breath, cough

Timepoint

Before starting the intervention and Days 1, 3, 7 and 14

Method of measurement

Questionnaire

2**Description**

Blood o2 saturation

Timepoint

Before starting the intervention and Days 3 and 7

Method of measurement

Pulse oximetry device

+98 35 3820 3414

Email

owlia@ssu.ac.ir

Secondary outcomes

1

Description

Mortality

Timepoint

Day 14

Method of measurement

Questionnaire

2

Description

Hospitalization

Timepoint

Days 7 and 14

Method of measurement

Questionnaire

Intervention groups

1

Description

Intervention group: includes 30 patients who receive doxycycline every 12 hours for 7 days along with standard treatment.

Category

Treatment - Drugs

2

Description

Control group: Includes 30 patients receive placebo every 12 hours for 7 days along with standard treatment.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Sadoughi Hospital - Shahid Sadoughi University of Medical Sciences, Yazd

Full name of responsible person

Mohammad Bagher Owlia

Street address

School of Medicine, Yazd Shahid Sadoughi University of Medical sciences and Health Services, Shohadaye Gomnam Blv., Professor Hesabi Blv., Yazd, Iran

City

Yazd

Province

Yazd

Postal code

۸۹۱۶۹۷۸۴۷۷

Phone

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

Dr.Masoud Mirzaei

Street address

Yazd - Shahid Dr. Bahonar Square - Central Organization of Shahid Sadoughi University of Medical Sciences and Health Services Yazd

City

Yazd

Province

Yazd

Postal code

۸۹۱۶۹۷۸۴۷۷

Phone

+98 35 3146 2136

Email

mmirzaei@ssu.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Yazd 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

Yazd University of Medical Sciences

Full name of responsible person

Zohreh Akhoundi Meybodi

Position

Assistant Professor

Latest degree

Subspecialist

Other areas of specialty/work

Infectious diseases

Street address

Infectious Diseases Research Center Shahid Sadoughi General Hospital Shahid Sadoughi University of

Medical Sciences

City

Yazd

Province

Yazd

Postal code

۸۹۱۵۸۸۷۸۵۷

Phone

+98 35 3822 4000

Email

drzakhondie@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

Mohammad Bagher Owlia

Position

Professor

Latest degree

Subspecialist

Other areas of specialty/work

Rheumatology

Street address

Department of Internal Medicine, School of Medicine
Shahid Sadoughi General Hospital Shahid Sadoughi
University of Medical Sciences

City

Yazd

Province

Yazd

Postal code

۸۹۱۵۸۸۷۸۵۷

Phone

+98 35 3822 4000

Fax

+98 35 3822 4100

Email

mbowlia2@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Seyed Ruhollah Mousavinasab

Position

Resident

Latest degree

Specialist

Other areas of specialty/work

Medical Pharmacy

Street address

Zand Avenue, Namazi Square, Namazi hospital, Shiraz

City

Shiraz

Province

Fars

Postal code

71937-11351

Phone

+98 71 3647 4332

Fax

+98 71 3647 4326

Email

srmn48@gmail.com

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

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

Statistical Analysis Plan

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

Informed Consent Form

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

Clinical Study Report

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

Analytic Code

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

Data Dictionary

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