Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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)

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+98 71 3647 4332

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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 forth 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 ،
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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

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

1

Sponsor
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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
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
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Other areas of specialty/work
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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
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