

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Evaluation of effectiveness and safety of Doxycycline in combination with standard treatment on clinical improvement and outcome of Covid-19 patients: a clinical trial

Protocol summary

Study aim

Evaluation of safety and effectiveness of doxycycline in the treatment of hospitalized patients with Covid-19

Design

Open label phase 3 clinical trial with a control group and parallel groups on 180 randomized patients; Random Allocation Software was used for randomization.

Settings and conduct

This study will be performed on patients with Covid 19 in Firoozgar Hospital in Tehran and the efficacy of dioxycycline in them will be evaluated. Patients in both groups are treated with the standard protocol or dioxycycline, this study is not blinded and the necessary information will be collected using a checklist.

Participants/Inclusion and exclusion criteria

Inclusion criteria include age more than 18 years, definitive diagnosis of Covid 19 and having informed consent. Also, exclusion criteria included allergies to dioxycycline, chronic liver failure, chronic renal failure, history of lupus, history of porphyria, pregnancy or breastfeeding.

Intervention groups

Control group: Standard protocol will be used for ten days including daily oxygen with the rate of 5 to 7 liters per minute, observance of hygienic principles and subcutaneous use of heparin manufactured by Caspian Pharmaceutical Company 5000 units three times per day, for 10 days. Intervention group: In addition to the national standard treatment protocol, doxycycline 200 mg capsules made by Pars Behroozan Company are used initially and then doxycycline 100 mg capsules twice a day for 7 days.

Main outcome variables

need for ICU admission and duration of hospitalization

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201117049427N1**

Registration date: **2022-08-08, 1401/05/17**

Registration timing: **retrospective**

Last update: **2022-08-08, 1401/05/17**

Update count: **0**

Registration date

2022-08-08, 1401/05/17

Registrant information

Name

elnaz Sarkheyi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 5621 3583

Email address

elnazsarkheyi@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-12-05, 1399/09/15

Expected recruitment end date

2021-02-03, 1399/11/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of effectiveness and safety of Doxycycline in combination with standard treatment on clinical improvement and outcome of Covid-19 patients: a clinical trial

Public title

Effect of Doxycycline on clinical improvement and outcome in patients with COVID-19

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age higher than 18 years
Definitive diagnosis of Covid 19
Having informed satisfaction

Exclusion criteria:

Allergy to Doxycycline
Chronic liver disease
Chronic kidney disease
History of lupus
History of porphyria
Pregnancy and lactation

Age

From **18 years** old to **100 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **180**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, computer-aided random assignment method is used. The samples are determined using the random number table in the Random Allocation Software. Blocking and allocation sequence for concealment will be done by a person not involved in the research, the block size is 6. The allocation ratio will be (1:1) and they will be placed in two groups. Then, based on the obtained blocks and in the order of the allocation sequence, the drugs will be given to the patients.

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 Iran University of Medical Sciences

Street address

Iran University of Medical Sciences, next to Milad Tower, Hemmat Highway, Tehran

City

tehran

Province

Tehran

Postal code

۱۴۴۹۶۱۴۵۳۵

Approval date

2020-12-22, 1399/10/02

Ethics committee reference number

IR.IUMS.FMD.REC.1399.523

Health conditions studied

1

Description of health condition studied

Covid 19

ICD-10 code

B34.2

ICD-10 code description

Coronavirus infection, unspecified

Primary outcomes

1

Description

Duration of hospitalization

Timepoint

Before the intervention and 5 days after the intervention

Method of measurement

Checklist

2

Description

ICU admission

Timepoint

Before the intervention and 5 days after the intervention

Method of measurement

Checklist

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In addition to the national standard protocol and supportive therapies, they are treated with doxycycline capsules manufactured by Pars Behroozan company at a dose of 200 mg first day and then 100 mg every 12 hours daily with two glasses of water in a sitting position for 7 days.

Category

Treatment - Drugs

2

Description

Control group: They are treated with standard protocol including daily oxygen with the rate of 5 to 7 liters per minute, observance of hygienic principles and subcutaneous heparin produced by Caspian Pharmaceutical Company, 5000 units three times per day for 10 days.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Firoozgar hospital

Full name of responsible person

Elnaz Sarkheyi

Street address

Firoozgar Hospital, Behafarin Street, Valiasr Sq.,
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Dr. Hossein Keyvani

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Tower, Hemmat Highway, Tehran

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research-m@iums.ac.ir

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Iran 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

Iran University of Medical Sciences

Full name of responsible person

Elnaz Sarkheyi

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Internal Medicine

Street address

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Person responsible for scientific inquiries

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Position

Resident

Latest degree

Medical doctor

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