Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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 dixycycline 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 Sarkheyl

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 21 5621 3583

Email address
elnazsarkheyl@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 Sarkheyl
Street address
Firoozgar Hospital, Behafarin Street, Valiasr Sq., Tehran
City
Tehran
Province
Tehran
Postal code
1593747811
Phone
+98 21 5537 7131
Email
elnazsarkheyl@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Dr. Hossein Keyvani
Street address
Iran University of Medical Sciences, next to Milad Tower, Hemmat Highway, Tehran
City
Tehran
Province
Tehran
Postal code
۱۵۹۳۷۴۷۸۱۱
Phone
+98 21 5621 3583
Email
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 Sarkheyl
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
Internal Medicine
Street address
Firoozgar Hospital, Behafarin Street, Valiasr Sq., Tehran
City
Tehran
Province
Tehran
Postal code
۱۵۹۳۷۴۷۸۱۱
Phone
+98 21 5621 3583
Fax
Email
elnazsarkheyl@gmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Elnaz Sarkheyl
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
Internal Medicine
Street address
Firoozgar Hospital, Behafarin Street, Valiasr Sq., Tehran
City
Tehran
Province

Tehran

Postal code

۱۵۹۳۷۴۷۸۱۱

Phone

+98 21 5621 3583

Fax

Email

elnazsarkheyl@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Elnaz Sarkheyl

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Internal Medicine

Street address

Firoozgar Hospital, Behafarin Street, Valiasr Sq., Tehran

City

Tehran

Province

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Postal code

۱۵۹۳۷۴۷۸۱۱

Phone

+98 21 5621 3583

Fax

Email

elnazsarkheyl@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