

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 May 2026

Ivermectine effect in treatment of patients with COVID-19 disease

Protocol summary

Study aim

The effect of Ivermectin on COVID19 virus, studied in vitro and reported by Australian investigators. In this study we intend to verify the efficacy of Ivermectin on the effect of this drug on the on the course of this disease and possible prevention from ICU admission, intubation, and mortality as well as some laboratory hallmarks in this disease.

Design

After randomization to two groups of 25 individuals the subjects in treatment group will receive three doses of oral ivermectin 200 micrograms/Kg once every other day for 3 doses plus the usual national protocol of treatment for COVID-19 disease while the control group receive only the national treatment protocol. Clinical trial with be one-way blind, phase 3 trial. Clinical findings and physiological parameters of respiration and treatment outcome as well as the changes in laboratory findings will be recorded. The results of the study will be analyzed using SPSS software.

Settings and conduct

In this study, 25 patients with COVID 19 being admitted to ImamReza Hospital who do not meet the exclusion criteria and after matching the similar control group of patients with this disease, in addition to the usual care, will receive three doses of oral ivermectin 200 micrograms / kg once every other day for 3 doses.

Participants/Inclusion and exclusion criteria

50 patients with COVID 19 disease with no exclusion criteria Exclusion criteria: history of allergy to ivermectin current helminthic disease Severe CHF, arrhythmia, renal or hepatic failure, end stage malignancy or any other disease on discretion of the physician before randomization and recruitment.

Intervention groups

ivermectin

Main outcome variables

ICU admission, intubation and mechanical ventilation, and mortality as well as the changes in LDH, CRP, and NLR as a marker of disease activity and predictors of the

outcome in COVID-19 disease.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200818048444N3**

Registration date: **2021-06-20, 1400/03/30**

Registration timing: **retrospective**

Last update: **2021-06-20, 1400/03/30**

Update count: **0**

Registration date

2021-06-20, 1400/03/30

Registrant information

Name

Khalil Ansarin

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 41 3337 8093

Email address

dr.ansarin@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-12-02, 1399/09/12

Expected recruitment end date

2021-01-31, 1399/11/12

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Ivermectine effect in treatment of patients with COVID-19 disease

Public title

Ivermectine effect in treatment and prophylaxis of patients and exposed individuals with COVID-19

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients with diagnosis of COVID-19 disease

Exclusion criteria:

History of allergy to ivermectin, and evidence for current helminthic disease Advanced renal failure with GFR<30 Advanced liver failure Advanced malignancy Severe heart failure or active cardiac arrhythmia

Age

No age limit

Gender

Both

Phase

1

Groups that have been masked

No information

Sample size

Target sample size: 25

Randomization (investigator's opinion)

Randomized

Randomization description

After determining the eligibility criteria and obtaining informed consent from patients, they will be assigned into the study groups using the Balanced Block Randomization method generated by the designer of the study. The size of the blocks and random sequence generation process will not be clarified for the principal investigator and other researchers so that the allocation concealment will be fully established. In addition, randomization efficacy will be tested at the end of the study and those confounding variables with imbalanced distribution across the study groups will be adjusted through the multivariable models.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Single

Other design features**Secondary Ids**

empty

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

Regional Committee on Research Ethics (Studies in

Human Subjects)

Street address

No .2, Tabriz University of Medical Science. Golgasht st., Tabriz

City

Tabriz

Province

East Azarbaijan

Postal code

5166614766

Approval date

2020-07-20, 1399/04/30

Ethics committee reference number

IR.TBZMED.REC.1399.375

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

Covid-19 Disease

ICD-10 code

U07.1

ICD-10 code description

Covid-19 Disease

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

Patient mortality

Timepoint

Within 28 days after the onset of the disease

Method of measurement

Physician report

2**Description**

Transfer to ICU

Timepoint

Within 28 days after the onset of the disease

Method of measurement

Physician report

3**Description**

Intubation or mechanical ventilation

Timepoint

Within 28 days after the onset of the disease

Method of measurement

Physician report

Secondary outcomes**1****Description**

Improve clinical symptoms

Timepoint

Start treatment up to 28 days
Method of measurement
Physician report

2

Description
CRP value
Timepoint
Start treatment up to 28 days
Method of measurement
Measurements in serum

3

Description
LDH value
Timepoint
Start treatment up to 28 days
Method of measurement
Measurements in serum

4

Description
NLR value
Timepoint
Start treatment up to 28 days
Method of measurement
Measurement with CBCD

Intervention groups

1

Description
Intervention group: 3 doses of oral ivermectin 200 µg / kg once daily for 3 doses
Category
Treatment - Drugs

2

Description
Control group: The patients in the control group will receive the standard treatment recommended by ministry of health for this disease
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Reza Hospital
Full name of responsible person
Khalil Ansarin
Street address
Imam Reza Hospital, Golgasht str.
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Tabriz
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Postal code
5166614756
Phone
+98 41 3334 7054
Email
imamreza@tbzmed.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Ministry of Health
Full name of responsible person
Dr. Harirchi, Iraj
Street address
Ghods Town, Iran Sima St., between Flamek and Zarafshan, Headquarters of the Ministry of Health, Treatment and Medical Education
City
Tehran
Province
East Azarbaijan
Postal code
Phone
+98 21 8836 3560
Email
mardomi@behdasht.gov.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Ministry of Health
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
Tabriz University of Medical Sciences
Full name of responsible person
Dr. Khalil Ansarin
Position
Professor
Latest degree
Subspecialist

Other areas of specialty/work

Internal Medicine

Street addressTuberculosis and Lung Diseases Research Center,
Pashmineh Building, University St.**City**

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Full name of responsible person

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Web page addresshttps://isid.research.ac.ir/Khalil_Ansarin**Person responsible for updating data****Contact****Name of organization / entity**

Tabriz University of Medical Sciences

Full name of responsible person

Dr. Khalil Ansarin

Position

Professor

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All data can potentially be shared after unidentified individuals.

When the data will become available and for how long

Spring 1400

To whom data/document is available

Data is allowed for all researchers after submitting an access request and confirming it

Under which criteria data/document could be used

In order to use the data, researchers must first identify and send the required items and data upon request, after which the data will be delivered.

From where data/document is obtainable

By email dr.ansarin@gmail.com or postal code: 5142954481

What processes are involved for a request to access data/document

The researcher must state his request in a letter. After agreeing to his request, the data will be emailed to him in Excel or Spss.

Comments