Clinical Trial Protocol
Iranian Registry of Clinical Trials

02 Nov 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 idividuals 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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5166614756

Phone

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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

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East Azarbaijan

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Phone

+98 21 8836 3560

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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
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Person responsible for scientific inquiries

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Email
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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