

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 Jul 2026

Study of Ivermectin Effectiveness in treatment process, survival and cure rate of COVID-19 patients: a randomized clinical trial

Protocol summary

Study aim

Study of Ivermectin effectiveness in the treatment of COVID-19 patients

Design

Double-blind, randomized clinical trial with parallel control group, phase 2-3 on 60 patients.

Settings and conduct

The study will be conducted in the coronavirus ward of Razi Hospital in Rasht from April to July 2021. Sealed envelope web-page is used to allocate treatments to the two arms A and B. 60 patients will be placed in 15 blocks of 4. In intervention group (A) they will receive Ivermectin 12 mg/day (Four 3 mg Tablets) orally for 2 days + standard care for 10 days and in control group (B) they will receive (Four 3 mg Placebo tablets) orally for 2 days + standard care for 10 days. Concealment is done using the sealed envelope method.

Participants/Inclusion and exclusion criteria

All Covid-19 patients admitted to the coronavirus ward of Razi Hospital in Rasht for period of April to July 2021. Conditions for not entering the study: Lack of informed consent, Lack of patient cooperation.

Intervention groups

Intervention group: Ivermectin (Alborz-Daru) 12 mg/day (Four 3 mg Tablets) orally for 2 days + standard care for 10 days or hospital discharge (whichever comes first)
Control group: Four 3 mg Tablets orally for 2 days + standard care for 10 days or hospital discharge (whichever comes first)

Main outcome variables

The time required to improve clinical symptoms and paraclinical measures within 10 days of starting treatment

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200329046892N3**

Registration date: **2021-03-29, 1400/01/09**

Registration timing: **prospective**

Last update: **2021-03-29, 1400/01/09**

Update count: **0**

Registration date

2021-03-29, 1400/01/09

Registrant information

Name

Nematollah Ahangar

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 13 3369 0099

Email address

n.ahangar@gums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-04-09, 1400/01/20

Expected recruitment end date

2021-07-11, 1400/04/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Study of Ivermectin Effectiveness in treatment process, survival and cure rate of COVID-19 patients: a randomized clinical trial

Public title

Effect of ivermectin in COVID-19

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 All Covid-19 patients admitted to the coronavirus ward of Razi Hospital in Rasht for period of April to July 2021 Age greater than or equal to 18 years Patients admitted with the following criteria: fever (oral temperature greater than 37.2 ° C), dry cough, severe tiredness or dyspnea At least one of the following criteria : positive PCR OR lung involvement on chest X-ray / CT scan
Exclusion criteria:
 Lack of informed consent Lack of patient cooperation Having pulmonary embolism or intravascular thrombosis Any major drug interaction between routine patient's drugs with any of the study drugs Pregnancy and lactation Simultaneous presence in other research study

Age
From **18 years** old

Gender
Both

Phase
2-3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
It is a block randomization type and the block with size of 4. Randomization tool: sealedenvelope.com. 60 patients will be assigned in 15 blocks of 4. In intervention group (A) they will receive Ivermectin 12 mg/day (Four 3 mg Tablets) orally for 2 days + standard care for 10 days and in control group (B) they will receive (Four 3 mg Placebo tablets) orally for 2 days + standard care for 10 days. Concealment is done using the sealed envelope method.

Blinding (investigator's opinion)
Double blinded

Blinding description
In this study, participants (patients) and medical staff are kept blind to the specificity of study groups (Double-blinded). For this purpose, an independent person from the research team and an Infectious Diseases specialist prescribes the assigned codes to each patient. Efforts will be made to make the drug and placebo by one company to ensure the similarity. Study drugs will be placed in similar packages, and patients will receive pre-arranged interventions in the order in which they enter the study.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Guilan University of Medical Sciences

Street address

School of Medicine, Guilan University Complex, 7th Km Tehran Road

City

Rasht

Province

Guilan

Postal code

4199613769

Approval date

2021-03-03, 1399/12/13

Ethics committee reference number

IR.GUMS.REC.1399.624

Health conditions studied

1

Description of health condition studied

COVID-19

ICD-10 code

U07.1

ICD-10 code description

virus identified

2

Description of health condition studied

COVID-19

ICD-10 code

U07.2

ICD-10 code description

virus not identified; Clinically-epidemiologically diagnosed COVID-19; Probable COVID-19; Suspected COVID-19

Primary outcomes

1

Description

The time required to improve clinical symptoms within 10 days of treatment start

Timepoint

Daily from the first day of intervention

Method of measurement

Physical examination

Secondary outcomes

1

Description

Body temperature

Timepoint

Daily from the first day of intervention

Method of measurement

Thermometer

2

Description

Heart rate

Timepoint

Daily from the first day of intervention

Method of measurement

Pulse oxymeter

3

Description

Blood pressure

Timepoint

Daily from the first day of intervention

Method of measurement

Barometer

4

Description

Respiration rate

Timepoint

Daily from the first day of intervention

Method of measurement

Count

5

Description

SPO2

Timepoint

Daily from the first day of intervention

Method of measurement

Pulse-oxy mete

6

Description

Duration of hospitalization

Timepoint

Daily from the first day of intervention

Method of measurement

Record in the patient file

7

Description

Mortality

Timepoint

Daily from the first day of intervention

Method of measurement

Record in the patient file

8

Description

Creatine phosphokinase

Timepoint

Before intervention, Day 5 and Day 10

Method of measurement

International Federation of Clinical Chemistry (IFCC)

9

Description

C reactive protein

Timepoint

Before intervention, Day 5 and Day 10

Method of measurement

Turbidometry

10

Description

Erythrocyte sedimentation rate

Timepoint

Before intervention, Day 5 and Day 10

Method of measurement

Westergren method

Intervention groups

1

Description

Intervention group: Ivermectin (Alborz-Daru) 12 mg/day (Four 3 mg Tablets) orally for 2 days + standard care for 10 days or hospital discharge (whichever comes first)

Category

Treatment - Drugs

2

Description

Control group: Four 3 mg Tablets orally for 2 days + standard care for 10 days or hospital discharge (whichever comes first)

Category

Placebo

Recruitment centers

1

Recruitment center**Name of recruitment center**

Razi hospital

Full name of responsible person

Tofigh Yaghubi

Street address

Sardar Jangal Ave.

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4199613769
Phone
+98 13 3354 1001
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tofigh_yaghubi@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Rasht University of Medical Sciences
Full name of responsible person
Dr. Mohammadreza Naghipour
Street address
Shahid Siadati Ave.. Namju St.
City
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Guilan
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4144666949
Phone
+98 13 3333 6394
Email
research@gums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Rasht 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
Rasht University of Medical Sciences
Full name of responsible person
Nematollah Ahangar
Position
Associate Professor
Latest degree
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Other areas of specialty/work
Pharmacology

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Person responsible for updating data

Contact

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Phone

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Fax**Email**

n.ahangar@gums.ac.ir

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

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Yes - There is 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

Not applicable

Title and more details about the data/document

Data about primary outcome

When the data will become available and for how long

2 months after results published

To whom data/document is available

Researchers

Under which criteria data/document could be used

Requested by authenticated scientific centers and universities

From where data/document is obtainable

Dr. Nematollah Ahangar School of Medicine Email: n.ahangar@gums.ac.ir

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

Official request signed by highest executive is mandatory. Moreover, acceptable reasons should be noted

Comments