Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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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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
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Shahid Siadati Ave.. Namju St.
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Postal code
4144666949
Phone
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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
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Person responsible for updating data

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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
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