Clinical Trial Protocol
Iranian Registry of Clinical Trials

30 May 2026

Evaluation of the effect of Arbidol drug in the treatment of hospitalized patients with COVID-19

Protocol summary

Study aim

1- Determining the effect of Arbidol in the treatment of patients with Coronavirus hospitalized in Firoozgar hospital. 2- Determining the effect of therapy according to guidelines in treatment of patients with Coronavirus. 3- Comparison of effect of treatment of patients with Coronavirus in Firoozgar hospital between control and intervention groups.

Design

Two arm parallel group, phase 3 trial, with total sample size of 100, simple randomization using random blocks

Settings and conduct

100 COVID-19 patients, hospitalization in Firoozgar hospital are randomly divided into two groups of intervention and control.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age equal or greater than 18 years; Signing a consent form; Diagnosis of COVID-19 by chest CT-scan or RT-PCR test. Exclusion criteria: People with a history of allergies to this drug and / or a history of severe allergies; Patients who used Arbidol (Tablets, capsules, granules) before hospitalization; Women who are breastfeeding or pregnant, Respiratory failure, renal or liver failure, Anemia or thrombocytopenia, Coagulation disorders, patients who received immunosuppressive drugs during 3 months ago, congenital heart disease,, arrhythmia

Intervention groups

Patients in the control group will be given a standard treatment regimen including Kaletra (Lopinavir-Ritonavir) and Hydroxychloroquine according to guidlines. Patients in the intervention group will be given oral Hydroxychloroquine with Arbidol orally at a dose of 50 mg 3 times daily for 5 to 10 days.

Main outcome variables

Antipyretic rate; Improvement of complete blood count ESR and CRP tests; Virus negative conversion rate; Improvement of blood oxygen saturation and no adjuvant oxygen therapy; Improvement of chest X-Ray symptoms

General information

Reason for update

Due to the implementation requirements, the update has been made in accordance with the existing conditions.

Acronym

IRCT registration information

IRCT registration number: **IRCT20180725040596N2**
Registration date: **2020-04-18, 1399/01/30**
Registration timing: **prospective**

Last update: **2020-08-04, 1399/05/14**
Update count: **2**

Registration date

2020-04-18, 1399/01/30

Registrant information

Name
Nasir Dehghan
Name of organization / entity
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Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-04-29, 1399/02/10

Expected recruitment end date

2020-09-22, 1399/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of Arbidol drug in the treatment of hospitalized patients with COVID-19

Public title

Effect of Arbidol in treatment of COVID-19

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age equal or greater than 18 years Signing informed consent Diagnosis of COVID-19 by chest CT-scan or RT-PCR test

Exclusion criteria:

Respiratory failure People with a history of allergies to this drug and or a history of severe allergies Patients who used Arbidol (Tablets, capsules, granules) before hospitalization Women who are breastfeeding or pregnant Renal or liver function failure Anemia or thrombocytopenia Patient who received immunosuppressive drug during 3 months ago Congenital heart failure History of arrhythmia coagulation disorders

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

Method: Simple randomization. Unit: Individual. Tools: Random blocks How to build: Using 4 times Blocks (AABB, ABAB, ...) with random selection of block and reading from right to left Allocation concealment will be done by numbered drug cans that are numbered randomly. The cans will be the same weight and shape and will be prepared by an independent researcher.

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

Ethics Committee of Iran University of Medical Sciences, Hemmat expressways, Iran University of Medical sciences, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1449614535

Approval date

2020-04-14, 1399/01/26

Ethics committee reference number

IR.IUMS.REC.1399.090

Health conditions studied

1

Description of health condition studied

COVID-19

ICD-10 code

U07.1

ICD-10 code description

Coronavirus infection, unspecified

Primary outcomes

1

Description

Measurement of patients fever

Timepoint

Measurement of patient's body temperature at the beginning of the study and 7 days after starting treatment

Method of measurement

Thermometer

2

Description

Measurement of complete blood count test

Timepoint

Performing a complete blood cell count test at the beginning of the study and 7 days after starting treatment

Method of measurement

Blood test

3

Description

Determination of C-reactive protein test

Timepoint
Measurement of C-reactive protein level at the beginning of the study and 7 days after starting treatment
Method of measurement
Blood test

4

Description
chest CT Scan view symptoms
Timepoint
Patient's chest CT scan check at the beginning of the study and 30 days after starting treatment
Method of measurement
Taking a chest CT scan

5

Description
Measurement of blood oxygen saturation and no adjuvant oxygen therapy
Timepoint
Measurement of oxygen saturation level at the beginning of the study and 7 days after starting treatment
Method of measurement
Pulse oximeter

6

Description
hospital admission days
Timepoint
check daily
Method of measurement
observation

Secondary outcomes

1

Description
Measurement of erythrocyte sedimentation rate test
Timepoint
Measurement of erythrocyte sedimentation rate at the beginning of the study and 7 days after starting treatment
Method of measurement
Blood test

2

Description
Observing virological results
Timepoint
Measurement of patient's sputum viral load at the beginning of the study and 7 days after starting treatment
Method of measurement
Real-time polymerase chain reaction test

3

Description
Patient death
Timepoint
Check daily
Method of measurement
Observation

Intervention groups

1

Description
Intervention group: 50 patients with COVID-19 will be included in this group and their treatment regimen includes oral Hydroxychloroquine (first day 400 mg/BD and from second day 200 mg/BD) and Arbidol orally at a dose of 200 mg 3 times a day for 5 to 10 days.
Category
Treatment - Drugs

2

Description
Control group: Fifty COVID-19 patients in the control group will be given a treatment regimen of two Kaletra 200/50 mg tablets every 12 hours and Hydroxychloroquine sulfate (single dose 400 mg/ BD for first day) for 5 to 10 days.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Firoozgar hospital
Full name of responsible person
Dr. Mitra ranjbar
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Firoozgar hospital., Beh Afarin Ave., Karimkhan Ave., Valiasr Sq
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person

Dr Abbas Motevalian

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Iran University of Medical Sciences., Shahid Hemmat Highway

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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
80

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

2

Sponsor

Name of organization / entity
Presidential Transformation and Development Cooperation Center

Full name of responsible person
Doctor sirous vatankhah

Street address
No 8, East Avesta str, Sheikh Baha'i Square

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Grant name

Grant code / Reference number

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

Title of funding source
Presidential Transformation and Development Cooperation Center

Proportion provided by this source
20

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
Dr. Mitra Ranjbar

Position
Professor of Infectious Diseases and Tropical Medicine

Latest degree
Specialist

Other areas of specialty/work
Infectious diseases

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Person responsible for scientific inquiries

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Full name of responsible person
Dr. Marzieh Nojomi

Position
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Person responsible for updating data

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mnojomi@iums.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
Yes - There is 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
Yes - There is 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 be shared after patients have become unrecognizable.

When the data will become available and for how long
The information access will begin immediately after the results are shared.

To whom data/document is available
University researchers and industry professionals will be able to access the data.

Under which criteria data/document could be used
Individuals with official letters from research centers, research institutes, research institutes affiliated with the Ministry of Health, as well as scientific research institutes will be able to view without interference.

From where data/document is obtainable
Individuals should refer to the Prevention Medicine and Public Health Research Center of Iran University of Medical Sciences located in Tehran, Hemmat Highway, next to Milad Tower, School of Medicine, third floor to Ms. Neda Soleiman Vandi. Website address: www.pmph.iums.ac.ir Email: pmph@iums.ac.ir Phone number: 02186703350 Postal Code: 1449614535 Mailbox: 354-14665

What processes are involved for a request to access data/document
By sending an e-mail or sending a letter to the esteemed head of the Prevention Medicine and Public Health Research Center Iran University of Medical Sciences and presenting the reasons for their request so that they will receive the data in less than a month after examining their reasons and during the relevant legal procedure.

Comments