

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

27 Jun 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 guidelines. 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

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 8868 5162

##### Email address

dehghan.n@tak.iums.ac.ir

##### 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

##### **Street address**

Firoozgar hospital., Beh Afarin Ave., Karimkhan Ave., Valiasr Sq

##### **City**

Tehran

##### **Province**

Tehran

##### **Postal code**

1593747811

##### **Phone**

+98 21 8214 1600

##### **Email**

h\_firoozgar@yahoo.com

##### **Web page address**

## **Sponsors / Funding sources**

### **1**

#### **Sponsor**

##### **Name of organization / entity**

Iran University of Medical Sciences

##### **Full name of responsible person**

Dr Abbas Motevalian

**Street address**

Iran University of Medical Sciences., Shahid Hemmat Highway

**City**

Tehran

**Province**

Tehran

**Postal code**

1449614535

**Phone**

+98 21 86701

**Email**

PR@iums.ac.ir

**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

**City**

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**Province**

Tehran

**Postal code**

1995859611

**Phone**

+98 21 6100 6100

**Email**

Info@cpdi.ir

**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

**Street address**

Firoozgar hospital., Beh Afarin Ave., Karimkhan Ave., Valiasr Sq

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**Province**

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**Phone**

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**Email**

mitrearanjbar@yahoo.com

**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Iran University of Medical Sciences

**Full name of responsible person**

Dr. Marzieh Nojomi

**Position**

Professor of Community Medicine

**Latest degree**

Specialist

**Other areas of specialty/work**

Public Health/Community Medicine

**Street address**

Iran University of Medical Sciences., Shahid Hemmat Highway

**City**

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**Province**

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**Postal code**

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**Email**

mnojomi@iums.ac.ir

**Person responsible for updating data****Contact****Name of organization / entity**

Iran University of Medical Sciences

**Full name of responsible person**

Dr. Marzieh Nojomi

**Position**

Professor of Community Medicine

**Latest degree**

Specialist

**Other areas of specialty/work**

Public Health/Community Medicine

**Street address**

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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**

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 Vand. Website address: [www.pmph.iums.ac.ir](http://www.pmph.iums.ac.ir) Email: [pmph@iums.ac.ir](mailto: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**