

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

21 Mar 2023

### Evaluating effectiveness and safety of Umifenovir in the treatment (COVID-19)infection In patients referred to Tehran Imam Khomeini Hospital Complex

#### Protocol summary

##### Study aim

Evaluation of the effect of Arbidol in treatment of covid 19

##### Design

Clinical trial of Openlabel, Phase 3 in 60 patients. Patients will be divided into two groups without the need for hospitalization and risk factors. In the first group, in addition to supportive treatment, 200mg hydroxychloroquine tablets twice a day for at least 5 days, which may last up to 14 days depending on clinical conditions, and the second group, in addition to hydroxychloroquine 200mg every 12 hours, under Treatment with Arbidol 200mg capsules every 8 hours for 5 days, depending on the patient's clinical condition, may take up to 14 days.

##### Settings and conduct

Respiratory triage of Imam Khomeini Hospital Complex in Tehran. Patients with a definite or probable diagnosis of covid19 and having risk factor are divided into two groups for out patient treatment.

##### Participants/Inclusion and exclusion criteria

Patients diagnosed with COVID-19 infection based on PCR test for oropharyngeal and nasopharyngeal secretions and/or Specific pulmonary involvement in chest ct Most age is equal to 18 years The patient has PO tolerance. Gaining conscious satisfaction from the patient or first-degree relatives responsible for the patient. No pregnancy and breastfeeding Do not take antiarrhythmic drugs Lack of any history of drug sensitivity Lack of renal failure Lack of liver failure

##### Intervention groups

The first group (control) treated with Hydroxychloroquine  
The second group (intervention) treated with Hydroxychloroquine with Arbidol

##### Main outcome variables

Cough; Fever; Dyspnea; Decreased appetite; Nausea; Vomit; Myalgia

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20200523047550N1**

Registration date: **2020-06-06, 1399/03/17**

Registration timing: **retrospective**

Last update: **2020-06-06, 1399/03/17**

Update count: **0**

##### Registration date

2020-06-06, 1399/03/17

##### Registrant information

##### Name

Sara Ghaderkhani

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 6658 1598

##### Email address

sghaderkhani@sina.tums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-04-20, 1399/02/01

##### Expected recruitment end date

2020-05-21, 1399/03/01

##### Actual recruitment start date

2020-04-20, 1399/02/01

##### Actual recruitment end date

2020-05-19, 1399/02/30

##### Trial completion date

2020-05-25, 1399/03/05

## Scientific title

Evaluating effectiveness and safety of Umifenovir in the treatment (COVID-19)infection In patients referred to Tehran Imam Khomeini Hospital Complex

## Public title

Effect of Umifenovir in treatment of covid-19

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

Patients diagnosed with COVID-19 infection based on PCR test for oropharyngeal and nasopharyngeal secretions or specific lung involvement in chest CT Age over 18 years The patient has PO tolerance Gaining conscious satisfaction from the patient or first-degree relatives responsible for the patient No pregnancy and breastfeeding

### Exclusion criteria:

Alt more than five times normal Renal failure History of any drug allergies Pregnancy and lactation Use of antiarrhythmic drugs

## Age

From 18 years old

## Gender

Both

## Phase

3

## Groups that have been masked

No information

## Sample size

Target sample size: 50

Actual sample size reached: 50

## Randomization (investigator's opinion)

Not randomized

## Randomization description

## 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

Tehran University of Medical Sciences, Vice Chancellor for Research

##### Street address

Keshavarz Boulevard, corner of Quds Street, Central University Organization, sixth floor, Deputy of Research and Technology

##### City

Tehran

## Province

Tehran

## Postal code

1417653761

## Approval date

2020-04-12, 1399/01/24

## Ethics committee reference number

IR.TUMS.VCR.REC.1399.204

## Health conditions studied

### 1

#### Description of health condition studied

covid 19

#### ICD-10 code

B34.2

#### ICD-10 code description

Coronavirus infection, unspecified

## Primary outcomes

### 1

#### Description

Percentage of people improved with arbidol

#### Timepoint

5, 7 and 14 days after taking Arbidol

#### Method of measurement

follow up with phone

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: Patients with probable or definitive diagnosis of covid 19 and have risk factor who have been treated with hydroxychloroquine also Received 200 mg arbidol capsule every 8 hours for 7 days. The company of the pharmaceutical is the Pharmstandard.

#### Category

Treatment - Drugs

### 2

#### Description

Control group: Patients with a probable or definitive diagnosis of covid 19 and a risk factor have been treated with hydroxychloroquine, on the first day, they were given 400 mg every 12 hours and then 200 mg every 12 hours for 7 days.

#### Category

Treatment - Drugs

## Recruitment centers

1

### Recruitment center

**Name of recruitment center**

Respiratory triage of Imam Khomeini Hospital Complex

**Full name of responsible person**

Sara Ghaderkhani

**Street address**

Keshavarz Boulevard, Imam Khomeini Hospital Complex

**City**

Tehran

**Province**

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**Postal code**

1417653761

**Phone**

+98 21 6694 7984

**Email**

sghaderkhani@sina.tums.ac.ir

## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Mohammad Ali Sahraeeyan

**Street address**

Keshavarz Boulevard, Corner of Quds St., Central Organization of Tehran University of Medical Sciences, 6th Floor

**City**

tehran

**Province**

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**Postal code**

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**Phone**

+98 21 8163 3619

**Fax**

+98 21 8163 3623

**Email**

rmo@tums.ac.ir

**Web page address**

<http://rmo.tums.ac.ir/>

**Grant name**

Covid 19 Grant

**Grant code / Reference number**

47251-101-1-99

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

Yes

**Title of funding source**

Tehran 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**

Tehran University of Medical Sciences

**Full name of responsible person**

Sara Ghaderkhani

**Position**

assistant professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Infectious diseases

**Street address**

Keshavarz Boulevard, Imam Khomeini Hospital Complex

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**Province**

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**Email**

sghaderkhani@sina.tums.ac.ir

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Sara Ghaderkhani

**Position**

Assistant Professor

**Latest degree**

Specialist

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

Tehran University of Medical Sciences

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assistant Professor

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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**

Undecided - It is not yet known if there will be 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**

Objectives of the research, Research Design, Results

**When the data will become available and for how long**

6 months after the publication of the results

**To whom data/document is available**

Physicians, researchers working in academic and scientific institutions

**Under which criteria data/document could be used**

Use in research

**From where data/document is obtainable**

My Email

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

Name and surname, medical system number, position, university name, email

**Comments**