

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

30 May 2026

### Evaluation of the efficacy and safety of Umifenovir in the treatment of hospitalized patients with covid-19: A randomized clinical trial

#### Protocol summary

##### Study aim

Evaluation of efficacy and safety of umifenovir in the treatment of the patients with covid-19

##### Design

Phase 3,2 arms each arms 50 patients, block randomization Two arm parallel group double blind randomised trial , one group as a placebo control group and another one intervention group, physicians and patients are blind

##### Settings and conduct

Sina hospital, randomize double blind(physicians and patients are blind) Patients are divided in two groups by Block Randomization method, one group as a placebo control group and another one as an intervention group

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: -age>18 -Patients with probable and definitive diagnosis of covid-19 -Presence of at least one clinical sign(fever,chill,myalgia,cough) with positive virologic specimen response or imaging findings for covid-19 Exclusion criteria: -Patients or companion dissatisfaction to enter or continue the study -History or symptoms for hypersensitivity to drug -Pregnancy/lactation

##### Intervention groups

Intervention group: Hydroxychloroquine 400 mg every 12 hours in the first day then 200 mg every 12 hours ,Atazanavir/Ritonavir 300/100 mg once daily, Uumifenovir 100 mg 2 capsules every 6 hours. Control group: Hydroxychloroquine 400 mg every 12 hours for the first day then 200 mg every 12 hours Atazanavir / ritonavir 300/100 mg, two placebo capsules (hand made) every 6 hours.

##### Main outcome variables

Clinical improvement includes Fever rupture,Spo2 >93 ,Improvement of respiratory symptoms.

#### General information

##### Reason for update

##### Acronym

#### IRCT registration information

IRCT registration number: **IRCT20200322046833N1**

Registration date: **2020-04-03, 1399/01/15**

Registration timing: **registered\_while\_recruiting**

Last update: **2020-04-14, 1399/01/26**

Update count: **1**

#### Registration date

2020-04-03, 1399/01/15

#### Registrant information

##### Name

Farhad Najmeddin

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 6695 4709

##### Email address

f-najmeddin@sina.tums.ac.ir

#### Recruitment status

**Recruitment complete**

#### Funding source

#### Expected recruitment start date

2020-03-28, 1399/01/09

#### Expected recruitment end date

2020-04-20, 1399/02/01

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

Evaluation of the efficacy and safety of Umifenovir in the treatment of hospitalized patients with covid-19: A randomized clinical trial

**Public title**

Umifenovir effectiveness in the treatment of COVID-19

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Age >18 years old Patients with a probable and definitive diagnosis of COVID-19 who are candidates for hospitalization and receiving antiviral regimens.

Presence of at least one clinical sign (including fever, chills, cough, myalgia) with positive virologic specimen or imaging findings for COVID-19

**Exclusion criteria:**

Patient or fellows' dissatisfaction with entering or continuing the study History or any signs of hypersensitivity to umifenovir Pregnancy and lactation

**Age**

From **18 years** old

**Gender**

Both

**Phase**

3

**Groups that have been masked**

- Participant
- Care provider
- Investigator
- Outcome assessor

**Sample size**

Target sample size: **100**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

In this study, we will use block randomization methods using four patents blocks that randomized by ( RAND) function in Excel .The patient code table is provided to the analyzer and will be used for analysis after completion of the study.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

In this study: The patient, the physician, the nurses, and the researchers are blind. The data analyst knows the details of the treatment regimen.

**Placebo**

Used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics committee of Tehran university of medical

sciences

**Street address**

Tehran university of medical sciences, Enghelab Ave, Enghelab square, Tehran

**City**

Tehran

**Province**

Tehran

**Postal code**

۱۴۱۷۶۱۴۴۱۱

**Approval date**

2020-03-17, 1398/12/27

**Ethics committee reference number**

IR.TUMS.VCR.REC.1398.1037

**Health conditions studied****1****Description of health condition studied**

Covid-19

**ICD-10 code**

U07.1

**ICD-10 code description**

Covid-19

**Primary outcomes****1****Description**

Clinical improvement includes fever rupture

**Timepoint**

Since admission to the hospital then daily monitoring

**Method of measurement**

Physical examination, thermometer, questionnaire

**2****Description**

Clinical improvement includes SPO2 >93%

**Timepoint**

Since admission to the hospital then daily monitoring

**Method of measurement**

Physical examination, pulse oxymetry,questionnaire

**3****Description**

Improvement of respiratory symptoms

**Timepoint**

Since admission to the hospital then daily monitoring

**Method of measurement**

Physical examination, ct scan,questionnaire

**4****Description**

Adverse effects

**Timepoint**

Since admission to the hospital then daily monitoring

**Method of measurement**

Questionnaire, physical examination

## Secondary outcomes

### 1

#### Description

Duration of hospitalization

#### Timepoint

7 days to 1 months after beginning the treatment

#### Method of measurement

Questionnaire

### 2

#### Description

Clinical outcome

#### Timepoint

7 days to 1 months after beginning the treatment

#### Method of measurement

Questionnaire

### 3

#### Description

Lipoxin

#### Timepoint

day-0, day-2, day-4

#### Method of measurement

measuring the plasma concentration of the biomarker with ELISA kit

### 4

#### Description

prostaglandin

#### Timepoint

day-0, day-2, day-4

#### Method of measurement

measuring the plasma concentration of the biomarker with ELISA kit

### 5

#### Description

leukotriene

#### Timepoint

day-0, day-2, day-4

#### Method of measurement

measuring the plasma concentration of the biomarker with ELISA kit

### 6

#### Description

resolvin

#### Timepoint

day-0, day-2, day-4

#### Method of measurement

measuring the plasma concentration of the biomarker with ELISA kit

## Intervention groups

### 1

#### Description

Intervention group: Hydroxychloroquine 400 mg every 12 hours for the first day then 200 mg every 12 hours Atazanavir / ritonavir 300/100 mg once daily. Arbidol 100 mg(manufactured by Pharmstandard)2 capsules every 6 hours.

#### Category

Treatment - Drugs

### 2

#### Description

Control group: Hydroxychloroquine 400 mg every 12 hours for the first day then 200 mg every 12 hours Atazanavir / ritonavir 300/100 mg, two placebo capsules (hand made) every 6 hours.

#### Category

Placebo

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Sina hospital

##### Full name of responsible person

Azar Haddadi

##### Street address

Sina hospital, Hassan-abad square, Tehran

##### City

Tehran

##### Province

Tehran

##### Postal code

۱۱۳۶۷۶۹۱۱

##### Phone

+98 21 6104 0000

##### Email

hosp\_sina@sina.tums.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Center for Progress and Development of Iran

##### Full name of responsible person

Morteza Pirali

##### Street address

Iran Tehran, Iran P.O.

##### City

Tehran

##### Province

Tehran

##### Postal code

19958-59611

**Phone**

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**Email**

hosp\_sina@sina.tums.ac.ir

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Center for Progress and Development of Iran

**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**

Other

**Person responsible for general inquiries****Contact****Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Bitah Shahrami

**Position**

Clinical pharmacist

**Latest degree**

Specialist

**Other areas of specialty/work**

Medical Pharmacy

**Street address**

Sina hospital, Hassan-abad square

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**Postal code**

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**Phone**

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**Email**

bita.shahrami@gmail.com

**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Farhad Najmeddin

**Position**

Clinical pharmacist

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Medical Pharmacy

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**Province**

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**Email**

f-najmeddin@sina.tums.ac.ir

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

Tehran University of Medical Sciences

**Full name of responsible person**

Behnam Bayatani

**Position**

Pharmacist

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Medical Pharmacy

**Street address**

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**City**

Tehran

**Province**

Tehran

**Postal code**

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**Phone**

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**Email**

Behnam.ba75@gmail.com

**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

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

**Study Protocol**

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

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

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

make this available