

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Evaluation the efficacy and safety of Umifenovir (Arbidol) Administration in comparison with Lopinavir-ritonavir (Kaletra) in COVID-19 patients

#### Protocol summary

##### Study aim

Evaluating the efficacy and safety of Umifenovir Administration in comparison with Lopinavir-ritonavir in COVID-19 patients

##### Design

Clinical trial with parallel randomized groups

##### Settings and conduct

Dr. Masih Daneshvari Hospital

##### Participants/Inclusion and exclusion criteria

In this study, patients who were between 18 and 100 years old, confirmed COVID-19 with RT-PCR, and signed the informed consent form included. Also, patients with chronic kidney disease, acute kidney Injury, chronic liver disease, mild cases of COVID-19 (outpatients) or critical cases of COVID-19 (needs to ICU or invasive mechanical ventilation), excluded.

##### Intervention groups

Patients in Umifenovir received Umifenovir at dose of 200 mg TDS for 7 days. In control group, patients received Lopinavir-ritonavir at dose of 200-50 mg in 2 tablets BID for 7 days. Both groups received oxygen therapy and other supportive interventions.

##### Main outcome variables

Fever: Cough: Dyspnea

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20151227025726N15**

Registration date: **2020-05-18, 1399/02/29**

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

Last update: **2020-05-18, 1399/02/29**

Update count: **0**

##### Registration date

2020-05-18, 1399/02/29

#### Registrant information

##### Name

Farzaneh Dastan

##### Name of organization / entity

Shahid Beheshti University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 912 270 5933

##### Email address

f\_dastan@sbmu.ac.ir

#### Recruitment status

##### Recruitment complete

#### Funding source

##### Expected recruitment start date

2020-04-08, 1399/01/20

##### Expected recruitment end date

2020-07-08, 1399/04/18

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

#### Scientific title

Evaluation the efficacy and safety of Umifenovir (Arbidol) Administration in comparison with Lopinavir-ritonavir (Kaletra) in COVID-19 patients

#### Public title

Evaluating the effects of Umifenovir (Arbidol) in COVID-19

#### Purpose

Treatment

#### Inclusion/Exclusion criteria

##### Inclusion criteria:

Laboratory confirmed COVID-19 with RT-PCR Oxygen saturation < 93% Fever more than 72 hours before admission Bilateral pulmonary infiltration Age over 18

years old

**Exclusion criteria:**

Chronic kidney disease (Stage IV and V) Acute kidney injury Pregnancy or breastfeeding Drug allergy history Chronic liver disease (Child pugh C) Mild phase of COVID-19 Critical phase of COVID-19

**Age**

From **18 years** old to **100 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**

Block randomization method was used in this study. 25 blocks including 4 patients generated with online website. In each block, two patients will be assigned to Umifenovir group and two patients will be assigned to Lopinavir-ritonavir group.

**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**

Vice-Chancellor in Research Affairs - Shahid Beheshti University of Medical Sciences

**Street address**

3 rd floor, School of Medicine, Evin St, Shahid Chamran Highway

**City**

Tehran

**Province**

Tehran

**Postal code**

1983963113

**Approval date**

2020-04-06, 1399/01/18

**Ethics committee reference number**

IR.SBMU.RETECH.REC.1399.030

**Health conditions studied**

**1**

**Description of health condition studied**

COVID-19 pneumonia

**ICD-10 code**

U07.1

**ICD-10 code description**

COVID-19, virus identified

**Primary outcomes**

**1**

**Description**

Fever

**Timepoint**

Daily

**Method of measurement**

Thermometer

**2**

**Description**

Cough

**Timepoint**

Daily

**Method of measurement**

Observation

**3**

**Description**

Dyspnea

**Timepoint**

Daily

**Method of measurement**

Observation

**Secondary outcomes**

**1**

**Description**

Hospitalization duration

**Timepoint**

At admission time and discharge time

**Method of measurement**

Clinical records

**2**

**Description**

Lung radiology changes

**Timepoint**

At admission time and seven and 14 days later

**Method of measurement**

Computed tomography

**3**

**Description**

Adverse drug reaction

**Timepoint**

Daily  
**Method of measurement**  
Observation

#### 4

**Description**  
Virological clearance  
**Timepoint**  
At admission time and seven and 14 days later  
**Method of measurement**  
Reverse transcription polymerase chain reaction

#### 5

**Description**  
Death  
**Timepoint**  
At the end of the study  
**Method of measurement**  
Medical record

#### 6

**Description**  
Need of mechanical ventilation  
**Timepoint**  
Daily  
**Method of measurement**  
Medical record

### Intervention groups

#### 1

**Description**  
Intervention group: Patients in Umifenovir received Umifenovir 200 mg TDS for 7 days.  
**Category**  
Treatment - Drugs

#### 2

**Description**  
Control group: Patients received Lopinavir-Ritonavir 50-200 mg in 2 Tab BID for 7 days.  
**Category**  
Treatment - Drugs

### Recruitment centers

#### 1

**Recruitment center**  
**Name of recruitment center**  
Masih Daneshvari Hospital  
**Full name of responsible person**  
Payam Tabarsi  
**Street address**  
Daraabad, Shahid Bahonar St. (Niavaran), Masih Daneshvari Hospital  
**City**

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1956944413  
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payamtabarsi@yahoo.com

### Sponsors / Funding sources

#### 1

**Sponsor**  
**Name of organization / entity**  
Shahid Beheshti University of Medical Sciences  
**Full name of responsible person**  
Afshin Zarghi  
**Street address**  
3rd floor, School of Medicine, Evin St, Shahid Chamran Highway  
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+98 21 23871  
**Email**  
mpd@sbm.ac.ir  
**Grant name**  
**Grant code / Reference number**  
**Is the source of funding the same sponsor organization/entity?**  
Yes  
**Title of funding source**  
Shahid Beheshti 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**  
Shahid Beheshti University of Medical Sciences  
**Full name of responsible person**  
Payam Tabarsi  
**Position**  
Professor  
**Latest degree**  
Subspecialist

**Other areas of specialty/work**

Infectious diseases

**Street address**

Dr. Masih Daneshvari Hospital, Daar-Abad, Niavaran

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tabarsi@nritld.ac.ir

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

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Farzaneh Dastan

**Position**

Assistant Professor, Clinical Pharmacy Specialist

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Medical Pharmacy

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Valieasr St., Intersection of Niyayesh Highway, Shahid Beheshti University of Medical Sciences, Faculty of Pharmacy

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

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Ali Saffaei

**Position**

Clinical Pharmacy Resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Medical Pharmacy

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**Email**

alisaffaei.ss@gmail.com

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

Yes - There is 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

**Title and more details about the data/document**

All potential data can be shared after blinding

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

Six months after publishing

**To whom data/document is available**

Researchers working in academic institutions

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

For research purposes and meta-analysis studies

**From where data/document is obtainable**

Dr. farzaneh Dastan, Dr. Masih Daneshvari Hospital, Daar-Abad, Niavaran

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

Official letter to the researchers

**Comments**