Clinical Trial Protocol
Iranian Registry of Clinical Trials

29 Oct 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 Umifenoviri Administration in comparison with Lopinavir-ritonavir in COVID-19 patients
Design
Clinical trial with parallel randomized groups
Settings and conduct
Dr. Masih Daneshvari Hopital
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
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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
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Daraabad, Shahid Bahonar St. (Niavaran), Masih Daneshvari Hospital
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
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3rd floor, School of Medicine, Evin St, Shahid Chamran 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
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
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Person responsible for updating data

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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 mounts 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