Clinical Trial Protocol
Iranian Registry of Clinical Trials

30 May 2026

Investigating the efficacy and safety of Umifenovir in controlling the symptoms of patients with COVID-19

Protocol summary

Study aim
Evaluation of the efficacy and safety of Umifenovir in control the respiratory symptoms of patients with COVID-19

Design
This study is a single-center, prospective, randomized, open-labeled, controlled,parallel phase 3 clinical trial.

Settings and conduct
Patients admitted to Baqiyatallah hospital, who are met the inclusion criteria, is entered to the study are randomly assigned into two groups of intervention and control.

Participants/Inclusion and exclusion criteria
Inclusion Criteria: 1.Age ≥18 years; 2. Announcing written and informed written consent to participate in the study. 3. Laboratory (RT-PCR) confirmation. 4.lung CT-Scan confirmation, which is typical for COVID-19 pulmonary involvement. 5. O2 saturation<93% on room air, at rest. Exclusion Criteria: 1. Hypersensitivty reaction to Umifenovir; 2. Concurrent treatment with other agents with actual or possible direct acting antiviral activity against SARS-CoV-2. 3. patient with at least one of these underlying disease: congenital heart disease, congestive heart failure, coronary artery disease, severe heart rhythm disorders, serious neurological diseases such as stroke, epilepsy, mental retardation, spinal cord injury. 4. Patients with immunodeficiency, including malignancy, HIV, organ transplantation, receiving immunosuppressive drugs in the last 3 months. 5. pregnancy or lactation; 6. involvement to another clinical study.7. Patient with critical condition (shock, respiratory failure, multi-organ failure)

Intervention groups
intervention group: Capsule Umifenovir 100mg, 2 Capsules every 6 hours, for 7 days (In addition to routine COVID-19 treatment based on the latest national guideline for the treatment of new corona virus) Control group:routine COVID-19 treatment based on the latest national guideline for the treatment of new corona virus.

Main outcome variables
clinical symptoms changes (dry cough, respiratory distress, fever)

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20080901001165N46**
Registration date: **2020-04-15, 1399/01/27**
Registration timing: **registered_while_recruiting**

Last update: **2020-04-15, 1399/01/27**
Update count: **0**

Registration date
2020-04-15, 1399/01/27

Registrant information

Name
Yunes Panahi

Name of organization / entity
Baqiyatallah University of Medical Sciences

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-03-30, 1399/01/11

Expected recruitment end date
2020-08-22, 1399/06/01

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Investigating the efficacy and safety of Umifenovir in controlling the symptoms of patients with COVID-19

Public title
Investigating the efficacy and safety of Umifenovir in controlling the symptoms of patients with COVID-19
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
age >18 years The patient have written consciously and freely consent to participate in the study. Confirmed diagnosis of COVID-19, with Laboratory (RT-PCR) confirmation. Confirmed diagnosis of COVID-19, with lung CT-Scan result, which is typical for COVID-19 pulmonary involvement. O2 saturation at rest in ambient air ≤93%
Exclusion criteria:
Concurrent treatment with other agents with actual or possible direct acting antiviral activity against SARS-CoV-2. Participation in any other clinical trial of an experimental treatment for COVID-19 Pregnant or breastfeeding; Hypersensitivity reaction history with Umifenovir. patient with critical stage of disease (respiratory failure, sock, multi organ dysfunction) patient with at least one of these disease as past medical history: congenital heart disease, Congestive heart failure, coronary artery disease, severe heart rhythm disorders, serious neurological disease including stroke, epilepsy, mental retardation, spinal cord injury. Patients with immunodeficiency, including malignancies, HIV, organ transplants, receiving immunosuppressive drugs in the last previous 3 months.
Age
From **18 years** old
Gender
Both

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **200**
Randomization (investigator's opinion)
Randomized
Randomization description
Block Randomization method is used to randomized the patients.
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 Baqiyatallah University of Medical Sciences
Street address
Baqyiatallah University of Medical Science, south Shekhi-Bahaei St., Mollasadra St., Vanak Sq., Tehran, Iran
City
Tehran
Province
Tehran
Postal code
1435916471
Approval date
2020-03-29, 1399/01/10
Ethics committee reference number
IR.BMSU.REC.1399.037

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
respiratory symptoms (dry cough)
Timepoint
Daily monitoring, but the result of baseline (before the initiation of intervention), and day 7 from the initiation, is recorded.
Method of measurement
Physical examination,questionnaire

2

Description
respiratory symptoms (respiratory distress)
Timepoint
Daily monitoring, but the result of baseline (before the initiation of intervention), and day 7 from the initiation, is recorded.
Method of measurement
pulse oxymetery device

3

Description
respiratory symptoms (fever)
Timepoint
Daily monitoring, but the result of baseline (before the initiation of intervention), and day 7 from the initiation, is recorded.
Method of measurement
Thermometer

Secondary outcomes

1

Description
radiologic finding changes in Lung CT-scan
Timepoint
before the intervention initiation (baseline), then at day 14
Method of measurement
Lung CT-scan

2

Description
lab tests changes
Timepoint
daily monitoring, but the before the intervention initiation (baseline) and day 7 results will recorded on designed checklist.
Method of measurement
blood sample, laboratory analysis

3

Description
mortality rate
Timepoint
day 14 of intervention initiation
Method of measurement
questionnaire

4

Description
Adverse Effects
Timepoint
daily monitoring, but the before the intervention initiation (baseline) and day 7 results will recorded on designed checklist.
Method of measurement
questionnaire, clinical examination

5

Description
Inflammatory biomarker level changes (including interleukin 1, interleukin 6, TNF alpha)
Timepoint
before the intervention initiation (baseline), then at day 7
Method of measurement
Elisa kit for Human

Intervention groups

1

Description
Intervention group: Capsule Umnifenovir 100 mg, 2 capsuls every 6 hours, for 7 days. (In addition to routine treatment according to the latest national guideline for the treatment of new corona-virus)
Category
Treatment - Drugs

2

Description
Control group: routine treatment according to the latest national guideline for the treatment of new corona-virus
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Baqiyatallah hospital
Full name of responsible person
Yunes Panahi
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Baqiyattalah hospital, Mollasadra st., Vanak sq., Tehran, Iran
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Center for Progress and Development of Iran
Full name of responsible person
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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
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
Parisa Kianpour
Position
Pharmacotherapy assistant
Latest degree
Specialist
Other areas of specialty/work
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Person responsible for updating data

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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