

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jul 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. Hypersensitivity 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 $\leq 93\%$

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

Baqiyatallah University of Medical Science, south Shekhi-Bahaei St., Mollasadra St., Vanak Sq., Tehran, Iran

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Province

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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 oxymetry 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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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

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Pharmacotherapy

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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