

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, Umifenovir 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

+98 21 6100 0000

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

City

Tehran

Province

Tehran

Postal code

113746911

Phone

+98 21 2244 5566

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

Street address

Sina hospital

City

Tehran

Province

Tehran

Postal code

113746911

Phone

+98 21 2233 4455

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

Sina hospital

City

Tehran

Province

Tehran

Postal code

113746911

Phone

+98 86 3314 1475

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