Clinical Trial Protocol
Iranian Registry of Clinical Trials

13 Nov 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 symtoms for hypersensivity to drug -Pregnancy/lactation

Intervention groups
Intervention group: Hydroxychlorquine 400 mg every 12 hours in the first day then 200 mg every 12 hours ,Atazanavir/Ritonavir 300/100 mg once daily, Uumifenovir 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 improvment includes Fever rupture,Spo2 >93 ,Improvment 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)

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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 oxymetery,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
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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
Morteza Pirali
Street address
Iran Tehran, Iran P.O.
City
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Province
Tehran
Postal code
19958-59611

Phone
+98 21 6100 0000
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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
Bita Shahrami
Position
Clinical pharmacist
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