

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Mar 2023

Evaluating effectiveness and safety of Umifenovir in the treatment (COVID-19)infection In patients referred to Tehran Imam Khomeini Hospital Complex

Protocol summary

Study aim

Evaluation of the effect of Arbidol in treatment of covid 19

Design

Clinical trial of Openlabel, Phase 3 in 60 patients. Patients will be divided into two groups without the need for hospitalization and risk factors. In the first group, in addition to supportive treatment, 200mg hydroxychloroquine tablets twice a day for at least 5 days, which may last up to 14 days depending on clinical conditions, and the second group, in addition to hydroxychloroquine 200mg every 12 hours, under Treatment with Arbidol 200mg capsules every 8 hours for 5 days, depending on the patient's clinical condition, may take up to 14 days.

Settings and conduct

Respiratory triage of Imam Khomeini Hospital Complex in Tehran. Patients with a definite or probable diagnosis of covid19 and having risk factor are divided into two groups for out patient treatment.

Participants/Inclusion and exclusion criteria

Patients diagnosed with COVID-19 infection based on PCR test for oropharyngeal and nasopharyngeal secretions and/or Specific pulmonary involvement in chest ct Most age is equal to 18 years The patient has PO tolerance. Gaining conscious satisfaction from the patient or first-degree relatives responsible for the patient. No pregnancy and breastfeeding Do not take antiarrhythmic drugs Lack of any history of drug sensitivity Lack of renal failure Lack of liver failure

Intervention groups

The first group (control) treated with Hydroxychloroquine
The second group (intervention) treated with Hydroxychloroquine with Arbidol

Main outcome variables

Cough; Fever; Dyspnea; Decreased appetite; Nausea; Vomit; Myalgia

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200523047550N1**

Registration date: **2020-06-06, 1399/03/17**

Registration timing: **retrospective**

Last update: **2020-06-06, 1399/03/17**

Update count: **0**

Registration date

2020-06-06, 1399/03/17

Registrant information

Name

Sara Ghaderkhani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 6658 1598

Email address

sghaderkhani@sina.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-04-20, 1399/02/01

Expected recruitment end date

2020-05-21, 1399/03/01

Actual recruitment start date

2020-04-20, 1399/02/01

Actual recruitment end date

2020-05-19, 1399/02/30

Trial completion date

2020-05-25, 1399/03/05

Scientific title

Evaluating effectiveness and safety of Umifenovir in the treatment (COVID-19)infection In patients referred to Tehran Imam Khomeini Hospital Complex

Public title

Effect of Umifenovir in treatment of covid-19

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients diagnosed with COVID-19 infection based on PCR test for oropharyngeal and nasopharyngeal secretions or specific lung involvement in chest CT Age over 18 years The patient has PO tolerance Gaining conscious satisfaction from the patient or first-degree relatives responsible for the patient No pregnancy and breastfeeding

Exclusion criteria:

Alt more than five times normal Renal failure History of any drug allergies Pregnancy and lactation Use of antiarrhythmic drugs

Age

From 18 years old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: 50

Actual sample size reached: 50

Randomization (investigator's opinion)

Not randomized

Randomization description

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

Tehran University of Medical Sciences, Vice Chancellor for Research

Street address

Keshavarz Boulevard, corner of Quds Street, Central University Organization, sixth floor, Deputy of Research and Technology

City

Tehran

Province

Tehran

Postal code

1417653761

Approval date

2020-04-12, 1399/01/24

Ethics committee reference number

IR.TUMS.VCR.REC.1399.204

Health conditions studied

1

Description of health condition studied

covid 19

ICD-10 code

B34.2

ICD-10 code description

Coronavirus infection, unspecified

Primary outcomes

1

Description

Percentage of people improved with arbidol

Timepoint

5, 7 and 14 days after taking Arbidol

Method of measurement

follow up with phone

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Patients with probable or definitive diagnosis of covid 19 and have risk factor who have been treated with hydroxychloroquine also Received 200 mg arbidol capsule every 8 hours for 7 days. The company of the pharmaceutical is the Pharmstandard.

Category

Treatment - Drugs

2

Description

Control group: Patients with a probable or definitive diagnosis of covid 19 and a risk factor have been treated with hydroxychloroquine, on the first day, they were given 400 mg every 12 hours and then 200 mg every 12 hours for 7 days.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Respiratory triage of Imam Khomeini Hospital Complex

Full name of responsible person

Sara Ghaderkhani

Street address

Keshavarz Boulevard, Imam Khomeini Hospital Complex

City

Tehran

Province

Tehran

Postal code

1417653761

Phone

+98 21 6694 7984

Email

sghaderkhani@sina.tums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Mohammad Ali Sahraeeyan

Street address

Keshavarz Boulevard, Corner of Quds St., Central Organization of Tehran University of Medical Sciences, 6th Floor

City

tehran

Province

Tehran

Postal code

1417653761

Phone

+98 21 8163 3619

Fax

+98 21 8163 3623

Email

rmo@tums.ac.ir

Web page address

<http://rmo.tums.ac.ir/>

Grant name

Covid 19 Grant

Grant code / Reference number

47251-101-1-99

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Tehran 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**

Tehran University of Medical Sciences

Full name of responsible person

Sara Ghaderkhani

Position

assistant professor

Latest degree

Specialist

Other areas of specialty/work

Infectious diseases

Street address

Keshavarz Boulevard, Imam Khomeini Hospital Complex

City

Tehran

Province

Tehran

Postal code

1419733141

Phone

+98 21 6694 7984

Email

sghaderkhani@sina.tums.ac.ir

Person responsible for scientific inquiries

Contact**Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Sara Ghaderkhani

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Infectious diseases

Street address

Keshavarz Boulevard, Imam Khomeini Hospital Complex

City

Tehran

Province

Tehran

Postal code

1419733141

Phone

+98 21 6694 7984

Email

sghaderkhani@sina.tums.ac.ir

Person responsible for updating data**Contact****Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Sara Ghaderkhani

Position

assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Infectious diseases

Street address

Keshavarz Boulevard, Imam Khomeini Hospital
Complex

City

Tehran

Province

Tehran

Postal code

1419733141

Phone

+98 21 6694 7984

Email

sghaderkhani@sina.tums.ac.ir

Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is 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

Yes - There is a plan to make this available

Title and more details about the data/document

Objectives of the research, Research Design, Results

When the data will become available and for how long

6 months after the publication of the results

To whom data/document is available

Physicians, researchers working in academic and scientific institutions

Under which criteria data/document could be used

Use in research

From where data/document is obtainable

My Email

What processes are involved for a request to access data/document

Name and surname, medical system number, position, university name, email

Comments