Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

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

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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

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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

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Person responsible for updating data

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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