Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jun 2026

Evaluating efficacy and safety of hydroxychloroquine + lopinavir or atazanavir/ritonavir combination in patients with COVID-19

Protocol summary

Study aim
Evaluating efficacy and safety of Hydroxychloroquine + Lopinavir or Atazanavir/ritonavir combination in patients with COVID-19

Design
This is a non-blinded, single group clinical trial.

Settings and conduct
Following data will be collected from admitted patients to Imam Khomeini hospital complex (according to the type of data at admission, daily or every other day) Chief complaint at admission Vital singes Baseline diseases History of drug use History of vaccination Hemodynamic parameters Oxygenation parameters Laboratory data Respiratory support requirement Supportive care Drug therapy Adverse drug reactions Duration of hospitalization Complications during hospitalization Clinical outcome

Participants/Inclusion and exclusion criteria
Inclusion criteria: Patients with highly suspected or confirmed COVID-19 who are candidate for hospitalization and starting triple-drug therapy Exclusion criteria: History of drug allergy, pregnancy and lactation

Intervention groups
Patients will receive Tab hydroxychloroquine 400 mg twice daily on day 1 then 200 mg twice daily + Tab lopinavir/ritonavir 200/50 mg two tablets twice daily or Tab atazanavir/ritonavir 300/100 mg daily for at least 5 days.

Main outcome variables
Clinical response Laboratory response Incidence rate of adverse drug reactions

General information

Reason for update
Edition of the interventions due to changes in the national protocol

Acronym

IRCT registration information
IRCT registration number: **IRCT20100228003449N30**
Registration date: **2020-03-22, 1399/01/03**
Registration timing: **registered_while_recruiting**

Last update: **2020-03-24, 1399/01/05**
Update count: **1**

Registration date
2020-03-22, 1399/01/03

Registrant information

Name
Hossein Khalili

Name of organization / entity
Tehran University of Medical Sciences

Country
Iran (Islamic Republic of)

Phone
+98 21 6695 4715

Email address
khalilih@tums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-03-15, 1398/12/25

Expected recruitment end date
2020-05-14, 1399/02/25

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluating efficacy and safety of hydroxychloroquine + lopinavir or atazanavir/ritonavir combination in patients with COVID-19

Public title
Combination therapy in COVID 19
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients with highly suspected or confirmed COVID-19 who are candid for hospitalization and starting triple-drug combination
Exclusion criteria:
History of drug allergy Pregnancy
Age
No age limit
Gender
Both

Phase
2-3
Groups that have been masked
No information
Sample size
Target sample size: **50**
Randomization (investigator's opinion)
N/A
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Single
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
Ghods Ave. Tehran University of Medical Sciences, Tehran, Iran
City
Tehran
Province
Tehran
Postal code
1417614411
Approval date
2020-03-15, 1398/12/25
Ethics committee reference number
IR.TUMS.VCR.REC.1398.1058

Health conditions studied

1

Description of health condition studied
COVID-19 pneumonia
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Clinical response
Timepoint
Every other day
Method of measurement
Evaluation of clinical signs and symptoms

2

Description
Paraclinical response
Timepoint
Every other day
Method of measurement
Laboratory and radiological findings

3

Description
Adverse drug reactions
Timepoint
Every other day
Method of measurement
Interview and laboratory data

Secondary outcomes

1

Description
Duration of hospitalization
Timepoint
End of hospitalization
Method of measurement
Medical records

2

Description
Clinical outcome
Timepoint
End of study
Method of measurement
Patient's record

Intervention groups

1

Description
Intervention group: Patients in this group will receive

drug regimen including Tab hydroxychloroquine 400 mg twice daily on day 1 then 200 mg twice daily + Tab lopinavir/ritonavir 200/50 mg two tablets twice daily or Tab atazanavir/ritonavir 300/100 mg daily for at least 5 days.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Imam Khomeini Hospital Complex
Full name of responsible person
Hossein Khalili
Street address
Keshavarz Boulveard
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۱۴۱۹۷۳۳۱۴۱
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Mohammad Ali Sahraian
Street address
Vice Chancellor for Research, Tehran University of Medical Sciences, Ghods Ave., Tehran, Iran
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02166706141
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msahrai@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
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
Hossein Khalili
Position
Professor
Latest degree
Specialist
Other areas of specialty/work
Medical Pharmacy
Street address
Department of Clinical Pharmacy, Faculty of Pharmacy, Tehran University of Medical Sciences, 16 Azar Ave., Tehran, Iran
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Person responsible for scientific inquiries

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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

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

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

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

Results of the study will be published. The study protocol and statistical analysis will be included in the manuscript

When the data will become available and for how long

One year after finishing the study, data will be published and will be available in databases

To whom data/document is available

After permission form the sponsor, data of the study will be available for academic researchers, physicians and scientific institutes

Under which criteria data/document could be used

Other researchers are permitted to included the results in their systematic reviews and metaanalysis

From where data/document is obtainable

For this you may ask Hossein Khalili through following information: Address: Department of Clinical Pharmacy, Faculty of Pharmacy, Tehran University of Medical Sciences, 16 Azar Ave.,Tehran, Iran Postal code: 1417614411 E-mail: khalilih@tums.ac.ir

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

After receiving the query, dependent on the requested data, the scientific responsible person of the study will response to the query in coordinate with the sponsor within 2 weeks

Comments

After receiving the query, dependent on the requested data, the scientific responsible person of the study will response to the query in coordinate with the sponsor within 2 weeks