

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 May 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 signs 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 Boulevard

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Tehran

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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

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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

Contact

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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