

# 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 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

**City**

Tehran

**Province**

Tehran

**Postal code**

۱۴۱۹۷۳۳۱۴۱

**Phone**

+98 21 6695 4515

**Email**

khalilih@tums.ac.ir

**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

**City**

Tehran

**Province**

Tehran

**Postal code**

02166706141

**Phone**

+98 21 8898 7381

**Email**

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

**City**

Tehran

**Province**

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**Postal code**

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**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Tehran University of Medical Sciences

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## Person responsible for updating data

### Contact

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Tehran University of Medical Sciences

**Full name of responsible person**

Hossein Khalili

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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