

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 2026

### Therapeutic Effect of Tenofovir and hydroxychloroquine combination therapy compared to chloroquine alone in patients with COVID-19

#### Protocol summary

##### Study aim

evaluating the effectiveness of tenofovir + hydroxychloroquine regiment compared to hydroxychloroquine alone in patients with COVID-19 pneumonia

##### Design

A randomized single-blinded superiority clinical trial with two parallel groups will carry out on 86 patients

##### Settings and conduct

This study will carry out on patients who were admitted to the acute respiratory disease ward of Ardabil Imam Khomeini hospital which is the referral hospital of the Ardabil province.

##### Participants/Inclusion and exclusion criteria

A total of 86 patients with COVID-19 induced pneumonia who have been diagnosed according to standard confirmatory tests will be enrolled in this study regarding the aforementioned inclusion and exclusion criteria.

##### Intervention groups

Patients will randomly allocate into two groups. Individuals in the study group will receive tenofovir + hydroxychloroquine, and patients in the control group will be treated just with hydroxychloroquine.

##### Main outcome variables

Alleviation of symptoms, recovery, and discharge;  
Deterioration of symptoms transfer to ICU; Death.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20200421047155N1**  
Registration date: **2020-04-25, 1399/02/06**  
Registration timing: **prospective**

Last update: **2020-04-25, 1399/02/06**

Update count: **0**

##### Registration date

2020-04-25, 1399/02/06

##### Registrant information

###### Name

Sina Parsay

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 45 3333 7332

###### Email address

sinaparsa91@gmail.com

##### Recruitment status

###### Recruitment complete

##### Funding source

##### Expected recruitment start date

2020-04-29, 1399/02/10

##### Expected recruitment end date

2020-06-20, 1399/03/31

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Therapeutic Effect of Tenofovir and hydroxychloroquine combination therapy compared to chloroquine alone in patients with COVID-19

##### Public title

Efficacy of tenofovir in covid-19

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

###### Inclusion criteria:

Patients with COVID-19 pulmonary infection Established diagnosis of COVID-19 with RTPCR Patients older than 18

years

**Exclusion criteria:**

Reinfection with COVID-19  
Pregnancy  
Patients with immunodeficiency  
Individuals who are reluctant to participate in study  
Prior history of allergy to used drugs  
Documented history of any other medical condition for which the patient require to use a certain medication routinely.  
Creatinin clearance less than 30 mg/min  
Oxygen Saturation (SpO2) less than 40%  
ICU patients

**Age**

From **18 years** old to **80 years** old

**Gender**

Both

**Phase**

3

**Groups that have been masked**

- Participant

**Sample size**

Target sample size: **86**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Each patient will be randomly allocated into one of the cases or study groups by using the "research randomizer" website facility.

**Blinding (investigator's opinion)**

Single blinded

**Blinding description**

All patients will remain unaware of in which group (study or control) they are.

**Placebo**

Not used

**Assignment**

Parallel

**Other design features**

**Secondary Ids**

empty

**Ethics committees**

**1**

**Ethics committee**

**Name of ethics committee**

Ethics committee of Ardabil University of Medical Science

**Street address**

Department of infectious disease, Imam Khomeini Hospital, Ataai Ave.

**City**

Ardabil

**Province**

Ardabil

**Postal code**

5614693361

**Approval date**

2020-04-18, 1399/01/30

**Ethics committee reference number**

IR.AUMS.REC.1399.051

**Health conditions studied**

**1**

**Description of health condition studied**

COVID-19

**ICD-10 code**

U07.1

**ICD-10 code description**

COVID-19, virus identified

**Primary outcomes**

**1**

**Description**

vital signs

**Timepoint**

daily

**Method of measurement**

direct physical examination

**2**

**Description**

body temperature

**Timepoint**

daily

**Method of measurement**

thermometer

**3**

**Description**

white blood cell count

**Timepoint**

daily

**Method of measurement**

blood sample analysis

**Secondary outcomes**

empty

**Intervention groups**

**1**

**Description**

Intervention group: PO Hydroxychloroquine 200 mg and PO tenofovir 300 mg once a day for 7 days

**Category**

Treatment - Drugs

**2**

**Description**

Control group: PO Hydroxychloroquine 200 mg once a day for 7 days

**Category**

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

**Name of recruitment center**

Imam Khomeini Hospital of Ardabil University of Medical Science

**Full name of responsible person**

Shahram Habibzadeh

**Street address**

Infectious disease ward, Imam Khomeini Hospital, Ataii Ave.

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**Postal code**

5618985991

**Phone**

+98 45 3353 4818

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**Email**

sinaparsa91@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Ardabil University of Medical Sciences

**Full name of responsible person**

Shahab Bohlooli

**Street address**

Research deputy, Ardabil University of Medical Science, Daneshgah Ave.

**City**

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**Province**

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**Postal code**

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**Phone**

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**Email**

shahab.bohlooli@arums.ac.ir

**Web page address**

<http://arums.ac.ir/vcresearch/fa>

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Ardabil 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**

Ardabil University of Medical Sciences

**Full name of responsible person**

Shahram Habibzadeh

**Position**

Associate professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Infectious diseases

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**Province**

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shahramhabibzadeh@gmail.com

## Person responsible for scientific inquiries

#### Contact

**Name of organization / entity**

Ardabil University of Medical Sciences

**Full name of responsible person**

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**Position**

Associate professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Infectious diseases

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## Person responsible for updating data

### Contact

**Name of organization / entity**

Ardabil University of Medical Sciences

**Full name of responsible person**

Sina Parsay

**Position**

Researcher

**Latest degree**

Medical doctor

**Other areas of specialty/work**

General Practitioner

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**Fax****Email**

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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**

Yes - There is 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**

All of the participants' data reported in the article relative to this trial after deidentification

**When the data will become available and for how long**

Immediately after publication regarding the publisher's policy

**To whom data/document is available**

Researchers who provide a methodologically sound proposal.

**Under which criteria data/document could be used**

Any purpose

**From where data/document is obtainable**

Shahram Habibzadeh shahramhabibzadeh@gmail.com  
Sina Parsay sinaparsa91@gmail.com

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

Proposals should be directed to one of the above-mentioned email addresses. Requestors also will need to sign a data access agreement.

**Comments**