

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 2026

### Evaluation of the therapeutic effect of colchicine plus chloroquine in comparison with chloroquine in patients with COVID-19

#### Protocol summary

##### Study aim

1. Evaluation of the therapeutic effect of colchicine plus chloroquine in comparison with chloroquine in patients with COVID-19 In terms of the outcome including mortality, transference to ICU and discharge
2. Evaluation of the therapeutic effect of colchicine plus chloroquine in comparison with chloroquine in patients with COVID-19 In terms of the hospitalization duration
3. Evaluation of the therapeutic effect of colchicine plus chloroquine in comparison with chloroquine in patients with COVID-19 In terms of the cessation of fever

##### Design

clinical trial, blinded, phase III, with control group, 100 patients divided into 2 groups, randomized using random number table.

##### Settings and conduct

This blinded clinical trial will be done in Imam Reza hospital of Ardabil on 100 COVID19 patients divided into 2 groups. the participants will be blinded to their regimen.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: 1. Pulmonary involvement seen in CT-Scan compatible with COVID19 2. Positive PCR of COVID19 Exclusion criteria: 1. Sensitivity to any medications of regimen 2. Renal failure 3. Heart diseases 4. Pregnancy 5. Reluctance to participate in the study

##### Intervention groups

Individuals of intervention group will receive 1 mg tablet of colchicine daily. The participants of the placebo group will receive a similar tablet without therapeutic effects.

##### Main outcome variables

Hospitalization duration; cessation of fever; outcome including mortality; transference to ICU and discharge

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20200418047126N1**

Registration date: **2020-05-14, 1399/02/25**

Registration timing: **registered\_while\_recruiting**

Last update: **2020-05-14, 1399/02/25**

Update count: **0**

##### Registration date

2020-05-14, 1399/02/25

##### Registrant information

###### Name

Farzad Salehzadeh

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 45 3371 7486

###### Email address

salehzadeh\_f@yahoo.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-05-04, 1399/02/15

##### 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

Evaluation of the therapeutic effect of colchicine plus chloroquine in comparison with chloroquine in patients with COVID-19

##### Public title

Evaluation of colchicine in treatment of coronavirus

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

Positive PCR for COVID19

### Exclusion criteria:

Sensitivity of patients to any medication that is in the regimen Renal failure Heart disease Pregnancy

## Age

From **18 years** old to **75 years** old

## Gender

Both

## Phase

3

## Groups that have been masked

- Participant

## Sample size

Target sample size: **100**

## Randomization (investigator's opinion)

Randomized

## Randomization description

Individuals will be divided into intervention or placebo group based on random number table

## Blinding (investigator's opinion)

Single blinded

## Blinding description

In this study the participants (patients) will be kept blind to the regimen

## Placebo

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 Sciences

##### Street address

Ardabil University of Medical Sciences, Daneshgah street

##### City

Ardabil

##### Province

Ardabil

##### Postal code

5618953141

#### Approval date

2020-04-18, 1399/01/30

#### Ethics committee reference number

IR.ARUMS.REC.1399.050

## Health conditions studied

### 1

#### Description of health condition studied

Pulmonary infection of COVID19

#### ICD-10 code

B34.2

#### ICD-10 code description

Coronavirus infection, unspecified

## Primary outcomes

### 1

#### Description

Hospitalization outcome

#### Timepoint

Last day of hospitalization in the section

#### Method of measurement

Calendar

### 2

#### Description

Fever cessation

#### Timepoint

Before hospitalization and 1, 3, 5, 7 days after hospitalization

#### Method of measurement

calendar

### 3

#### Description

Hospitalization time

#### Timepoint

First and last day of hospitalization

#### Method of measurement

Calendar

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: A 1 mg tablet of colchicine daily for 10 days

#### Category

Treatment - Drugs

### 2

#### Description

Control group: A placebo tablet daily for 10 days

#### Category

Placebo

## Recruitment centers

### 1

#### Recruitment center

**Name of recruitment center**

Imam Reza (pbuh) of Ardabil

**Full name of responsible person**

Farhad Salehzadeh

**Street address**

Ardabil University of Medical Sciences, Daneshgah street

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## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Ardabil University of Medical Sciences

**Full name of responsible person**

Haleh Valizadeh Haghi

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Research Vice Chancellorship section, Ardabil University of Medical Sciences, Daneshgah street

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h.valizadeh@arums.ac.ir

**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**

Farhad Pourfarzi

**Position**

professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Social medicine

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## Person responsible for scientific inquiries

#### Contact

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Farhad Salehzadeh

**Position**

Professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Pediatrics

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## Person responsible for updating data

#### 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**

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**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be 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**

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

**Clinical Study Report**

Undecided - It is not yet known if there will be 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