

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 2026

### Effect of plasma of patients recovered from covid-19 versus control group on treatment of covid-19: a randomized clinical trial

#### Protocol summary

Registration timing: **prospective**

#### Study aim

To assess the effect of plasma of patients recovered from covid-19 versus control group on treatment of covid-19

Last update: **2020-04-27, 1399/02/08**

Update count: **0**

#### Design

This is a randomized clinical trial, phase II, in which 100 eligible patients will be randomly assigned to the intervention and control groups

#### Registration date

2020-04-27, 1399/02/08

#### Settings and conduct

The eligible patients with covid-19 referring to the Sina Hospital in Hamadan city during the study period will be enrolled in the trial and will be randomly assigned to the intervention and control groups through the block randomization.

#### Registrant information

##### Name

Jalal Poorolajal

##### Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 81 1838 0090

##### Email address

poorolajal@umsha.ac.ir

#### Participants/Inclusion and exclusion criteria

Inclusion criteria: Age of 18 to 65 years, Moderate to severe covid-19 disease, Exclusion criteria: Pregnancy, IGA deficiency

#### Recruitment status

**Recruitment complete**

#### Funding source

#### Expected recruitment start date

2020-05-14, 1399/02/25

#### Expected recruitment end date

2020-06-20, 1399/03/31

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Intervention groups

Intervention group: Routine care (For outpatients: 250 mg chloroquine tablets every 12 hours for the first day and then every day for up to 6 days; for inpatients: tablet Lupinavir 200 mg and tablet Ritonavir 50 mg every 12 hours for 14 days) plus plasma of patients recovered from covid-19 500 U every week for at least 3 weeks  
Control group: Just routine care (For outpatients: 250 mg chloroquine tablets every 12 hours for the first day and then every day for up to 6 days; for inpatients: tablet Lupinavir 200 mg and tablet Ritonavir 50 mg every 12 hours for 14 days)

#### Main outcome variables

Primary outcome: Dyspnea, fever, cough with

#### Scientific title

Effect of plasma of patients recovered from covid-19 versus control group on treatment of covid-19: a randomized clinical trial

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20120215009014N353**

Registration date: **2020-04-27, 1399/02/08**

#### Public title

Effect of plasma of patients recovered from covid-19 versus control group on treatment of covid-19

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

Age of 18 to 65 years, Moderate to severe covid-19 disease,

### Exclusion criteria:

Pregnancy, IGA deficiency

## Age

From **18 years** old to **65 years** old

## Gender

Both

## Phase

2

## Groups that have been masked

*No information*

## Sample size

Target sample size: **100**

## Randomization (investigator's opinion)

Randomized

## Randomization description

The patients will be randomly assigned to intervention and control groups using block randomization. For this purpose, we will prepare four sheets of paper, writing on two sheets the name of the intervention and on the other two sheets the name of the control. The paper sheets will be pooled, placed in a container, and randomly drawn one at a time for each patient without replacement until all four sheets are drawn. The four paper sheets will be then placed back into the container, and this action repeated until the sample size is reached.

## Blinding (investigator's opinion)

Not blinded

## Blinding description

## Placebo

Not used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics Committee of Hamadan University of Medical Sciences

##### Street address

Vice-chancellor for Research and Technology,  
Hamadan University of Medical Sciences, Shahid Fahmideh Ave

##### City

Hamadan

##### Province

Hamadan

## Postal code

6517838695

## Approval date

2020-04-11, 1399/01/23

## Ethics committee reference number

IR.UMSHA.REC.1399.037

## 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

Dyspnea

#### Timepoint

Every day for 3 weeks

#### Method of measurement

With taking history and physical examination

### 2

#### Description

Fever

#### Timepoint

Every day for 3 weeks

#### Method of measurement

With physical examination

### 3

#### Description

Cough

#### Timepoint

Every day for 3 weeks

#### Method of measurement

With taking history

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: Routine care (For outpatients: 250 mg chloroquine tablets every 12 hours for the first day and then every day for up to 6 days; for inpatients: tablet Lupinavir 200 mg and tablet Ritonavir 50 mg every 12 hours for 14 days) plus plasma of patients recovered from covid-19 500 U every week for at least 3 weeks

**Category**

Treatment - Drugs

**2****Description**

Control group: Just routine care (For outpatients: 250 mg chloroquine tablets every 12 hours for the first day and then every day for up to 6 days; for inpatients: tablet Lupinavir 200 mg and tablet Ritonavir 50 mg every 12 hours for 14 days)

**Category**

N/A

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Sina Hospital in Hamadan city

**Full name of responsible person**

Samereh Ghelichkhani

**Street address**

Sina Hospital, Mirzadeh Eshghi Ave.

**City**

Hamadan

**Province**

Hamadan

**Postal code**

6517838695

**Phone**

+98 81 3827 4184

**Email**

sa.ghelichkhani@gmail.com

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Hamedan University of Medical Sciences

**Full name of responsible person**

Dr. Saeid Bashirian

**Street address**

Hamadan University of Medical Sciences, Shahid Fahmideh Ave

**City**

Hamadan

**Province**

Hamadan

**Postal code**

6517838695

**Phone**

+98 81 3838 0717

**Email**

info.research@umsha.ac.ir

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

Yes

**Title of funding source**

Hamedan 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**

Hamedan University of Medical Sciences

**Full name of responsible person**

Samereh Ghelichkhani

**Position**

MSc in Nursery

**Latest degree**

Master

**Other areas of specialty/work**

Nursery

**Street address**

School of Medicine, Hamadan University of Medical Sciences, Shahid Fahmideh Ave.

**City**

Hamadan

**Province**

Hamadan

**Postal code**

6517838695

**Phone**

+98 81 3838 0572

**Email**

sa.ghelichkhani@gmail.com

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

Hamedan University of Medical Sciences

**Full name of responsible person**

Dr. Ebrahim Jalili

**Position**

Emergency Medicine Specialist

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Emergency Medicine

**Street address**

School of Medicine, Hamadan University of Medical Sciences, Shahid Fahmideh Ave.

**City**

Hamadan

**Province**

Hamadan  
**Postal code**  
6517838695  
**Phone**  
+98 81 3838 0572  
**Email**  
jalili.dr@gmail.com

6517838695  
**Phone**  
+98 81 3838 0090  
**Email**  
poorolajal@umsha.ac.ir

## Person responsible for updating data

### Contact

**Name of organization / entity**  
Hamedan University of Medical Sciences  
**Full name of responsible person**  
Dr. Jalal Poorolajal  
**Position**  
Professor of Epidemiology  
**Latest degree**  
Ph.D.  
**Other areas of specialty/work**  
Epidemiology  
**Street address**  
School of Public Health, Hamadan University of  
Medical Sciences, Shahid Fahmideh Ave  
**City**  
Hamadan  
**Province**  
Hamadan  
**Postal code**

## 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