

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

19 Jun 2026

### Evaluating the efficacy and safety of intravenous immunoglobulin (IVIG) in COVID-19 patients

#### Protocol summary

##### Study aim

Determination of the efficacy and safety of IVIG in treatment of patients with COVID-19

##### Design

Prospective clinical trial with parallel randomized groups

##### Settings and conduct

Place of study: Masih Daneshvari Hospital. How to do the study: 80 patients with COVID-19 will be randomly divided in to intervention and control group.

##### Participants/Inclusion and exclusion criteria

Patients who are diagnosed with COVID-19 by RT-PCR test, who are severely ill, and are between 18 to 65 years old. Patients with oxygen saturation <90% (at rest with nasal cannula 3-4 L/min and FIO<sub>2</sub><30-40 L/min) with bilateral pulmonary infiltration were included in the study. Furthermore, patients with allergic reaction while injecting IVIG with severe extravasation and anaphylactic shock, and mildly ill patients were excluded from the study.

##### Intervention groups

Patients in treatment group will receive hydroxychloroquine 200 mg (Tehran Daroo) twice daily + Lopinavir/Ritonavir 200-50 mg (Hetero Labs Limited) 2 Tab twice daily for 7 days + IVIG (Biotest) 400 mg/Kg for 3 doses. patients in control group will only receive hydroxychloroquine 200 mg (Tehran Daroo) twice daily + Lopinavir/Ritonavir 200-50 mg (Hetero Labs Limited) 2 Tab twice daily for 7 days.

##### Main outcome variables

Need for mechanical ventilation, need of admission to critical care unit, and death.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20151227025726N20**

Registration date: **2020-07-26, 1399/05/05**

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

Last update: **2020-07-26, 1399/05/05**

Update count: **0**

##### Registration date

2020-07-26, 1399/05/05

##### Registrant information

###### Name

Farzaneh Dastan

###### Name of organization / entity

Shahid Beheshti University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 912 270 5933

###### Email address

f\_dastan@sbmu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-07-09, 1399/04/19

##### Expected recruitment end date

2020-08-09, 1399/05/19

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Evaluating the efficacy and safety of intravenous immunoglobulin (IVIG) in COVID-19 patients

##### Public title

Evaluating the effects of intravenous immunoglobulin (IVIG) in COVID-19 patients

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

Patients between 18 and 65 years old. Laboratory confirmed COVID-19 (Corona Virus Disease-19) with RT-PCR (Real-Time Polymerase Chain Reaction). Severely ill patients. Bilateral pulmonary infiltration. SPO2 (Peripheral Capillary Oxygen Saturation) less than 90% (at rest with nasal cannula 3-4 L/min and FIO2 less than 30-40 L/min). Signed consent form.

### Exclusion criteria:

Allergy reaction while injecting IVIG with severe extravasation and anaphylactic shock. Mildly ill patient. Pregnancy or breast feeding.

## Age

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

## Gender

Both

## Phase

2-3

## Groups that have been masked

*No information*

## Sample size

Target sample size: **80**

## Randomization (investigator's opinion)

Randomized

## Randomization description

Block randomization method was used in this study. Eight blocks including 10 patients generated with online website. In each block, five patients will be assigned to IVIG group and five patients will be assigned to control group.

## 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 Shahid Beheshti University of Medical Sciences

##### Street address

3 rd floor, School of Medicine, Evin St, Shahid Chamran Highway

##### City

Tehran

##### Province

Tehran

##### Postal code

1983963113

## Approval date

2020-07-07, 1399/04/17

## Ethics committee reference number

IR.SBMU.NRITLD.REC.1399.143

## Health conditions studied

### 1

#### Description of health condition studied

COVID-19 pneumonia

#### ICD-10 code

U07.1

#### ICD-10 code description

COVID-19, virus identified

## Primary outcomes

### 1

#### Description

Need for mechanical ventilation

#### Timepoint

Daily until discharge

#### Method of measurement

Medical record

### 2

#### Description

Need of admission to critical care unit

#### Timepoint

Daily until discharge

#### Method of measurement

Medical record

### 3

#### Description

Death

#### Timepoint

From first day of admission until 28 days

#### Method of measurement

Medical record

## Secondary outcomes

### 1

#### Description

Severity of symptoms

#### Timepoint

First day of study then 7 and 14 days after the beginning of the study

#### Method of measurement

Medical record

### 2

#### Description

Lung radiology changes

## Timepoint

At admission time and 7 and 14 days later

## Method of measurement

Computed tomography

## Intervention groups

### 1

#### Description

Intervention group: Patients in treatment group will receive hydroxychloroquine 200 mg (Tehran Daroo) twice daily + Lopinavir/Ritonavir 200-50 mg (Hetero Labs Limited) 2 Tab twice daily for 7 days + IVIG (Biotest) 400 mg/Kg for 3 doses.

#### Category

Treatment - Drugs

### 2

#### Description

Control group: patients will only receive hydroxychloroquine 200 mg (Tehran Daroo) twice daily + Lopinavir/Ritonavir 200-50 mg (Hetero Labs Limited) 2 Tab twice daily for 7 days.

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Masih Daneshvari Hospital

##### Full name of responsible person

Payam Tabarsi

##### Street address

Masih Daneshvari Hospital, Shahid Bahonar Street (Niyavaran), Darabad.

##### City

Tehran

##### Province

Tehran

##### Postal code

1956944413

##### Phone

+98 21 2712 3000

##### Email

payamtabarsi@yahoo.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Shahid Beheshti University of Medical Sciences

##### Full name of responsible person

Afshin Zarghi

##### Street address

3rd floor, School of Medicine, Evin St, Shahid

Chamran Highway

##### City

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##### Province

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##### Postal code

1983963113

##### Phone

+98 21 23871

##### Email

mpd@sbm.ac.ir

#### Grant name

#### Grant code / Reference number

#### Is the source of funding the same sponsor organization/entity?

Yes

#### Title of funding source

Shahid Beheshti 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

Shahid Beheshti University of Medical Sciences

##### Full name of responsible person

Payam Tabarsi

##### Position

Professor

##### Latest degree

Subspecialist

##### Other areas of specialty/work

Infectious diseases

##### Street address

Shahid Bahonar St., Darabad St

##### City

Tehran

##### Province

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##### Postal code

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##### Phone

+98 21 2610 5050

##### Email

payamtabarsi@yahoo.com

## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Farzaneh Dastan

**Position**

Assistant Professor, Clinical Pharmacy Specialist

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Medical Pharmacy

**Street address**

Faculty of Pharmacy, Shahid Beheshti University of  
Medical Sciences, Intersection of Niyayesh Highway,  
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**Phone**

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**Email**

z.mirshafei@gmail.com

**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**

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

**Title and more details about the data/document**

All potential data can be shared after blinding

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

Six months after publishing the results

**To whom data/document is available**

Researchers working in academic institutions

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

For research purposes and meta-analysis studies

**From where data/document is obtainable**

Dr. farzaneh Dastan, Dr. Masih Daneshvari Hospital,  
Daar-Abad, Niavaran

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

Official letter to the researchers

**Comments****Person responsible for updating data****Contact****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Zahra Mirshafiei Langari

**Position**

Hospital pharmacist

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Medical Pharmacy

**Street address**

Dr. Masih Daneshvari Hospital, Daar-Abad, Niavaran

**City**

Tehran

**Province**

Tehran

**Postal code**