

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

30 May 2026

### Evaluation the Efficacy and Safety of Tocilizumab in Patients with Novel Coronavirus (COVID-19)

#### Protocol summary

##### Study aim

Evaluation the Efficacy and Safety of Tocilizumab in Patients with Novel Coronavirus (COVID-19)

##### Design

Non-controlled clinical trial

##### Settings and conduct

Dr. Masih Daneshvari Hospital

##### Participants/Inclusion and exclusion criteria

Patients with confirmed COVID-19 who are in severe phase and did not have chronic kidney or liver diseases and are not pregnant or breastfeeder and high level of interleukin-6

##### Intervention groups

Patients receive Hydroxychloroquine 400 mg P.O. BID and Oseltamivir 75 mg P.O. BID and Lopinavir-Ritonavir 200/50 mg P.O. two tablets BID for five days. Also, patients receive Interferon beta-1a 44 mg every other day S.C until 10 days. Also, patients receive Tocilizumab at dose of 400 mg I.V infusion.

##### Main outcome variables

Clinical response to therapy

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20151227025726N13**

Registration date: **2020-03-26, 1399/01/07**

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

Last update: **2020-03-26, 1399/01/07**

Update count: **0**

##### Registration date

2020-03-26, 1399/01/07

##### 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

2020-03-11, 1398/12/21

##### Expected recruitment end date

2020-05-10, 1399/02/21

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Evaluation the Efficacy and Safety of Tocilizumab in Patients with Novel Coronavirus (COVID-19)

##### Public title

Evaluation the Efficacy and Safety of Tocilizumab in COVID-19

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

##### Inclusion criteria:

Laboratory confirmed COVID-19 with RT-PCR Respiratory rate > 30/min Oxygen saturation < 90% PaO2/FiO2 < 300mmHg High level of serum Interleukin-6 Age over 18 years old

##### Exclusion criteria:

Chronic kidney Disease Acute kidney injury Pregnancy or

breastfeeding Drug allergy history Pneumonia due to influenza virus, bacterial pneumonia, fungal pneumonia, and noninfectious causes Chronic liver disease History of latent or active tuberculosis Patients with human immunodeficiency virus

#### Age

From **18 years** old

#### Gender

Both

#### Phase

2

#### Groups that have been masked

*No information*

#### Sample size

Target sample size: **40**

#### 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

National Research Institute of Tuberculosis and Lung Diseases

##### Street address

Dr. Masih Daneshvari Hospital, Daar-Abad, Niavaran

##### City

Tehran

##### Province

Tehran

##### Postal code

19569-44413

#### Approval date

2020-03-10, 1398/12/20

#### Ethics committee reference number

IR.SBMU.NRITLD.REC.1399.002

## Health conditions studied

### 1

#### Description of health condition studied

COVID-19 pneumonia

#### ICD-10 code

RA01.0

#### ICD-10 code description

Confirmed diagnosis of COVID-19

## Primary outcomes

### 1

#### Description

Fever

#### Timepoint

Daily

#### Method of measurement

Thermometer

### 2

#### Description

Cough

#### Timepoint

Daily

#### Method of measurement

Observation

### 3

#### Description

Dyspnea

#### Timepoint

Daily

#### Method of measurement

Observation

## Secondary outcomes

### 1

#### Description

Hospitalization duration

#### Timepoint

At admission time and discharge time

#### Method of measurement

Clinical records

### 2

#### Description

Lung radiology changes

#### Timepoint

At admission time and seven and 14 days later

#### Method of measurement

Computed tomography

### 3

#### Description

Adverse Drug Reaction

#### Timepoint

Daily

#### Method of measurement

Observation

#### 4

##### **Description**

Virological clearance

##### **Timepoint**

At admission time and seven and 14 days later

##### **Method of measurement**

Reverse transcription polymerase chain reaction

### **Intervention groups**

#### 1

##### **Description**

Intervention group: Tab Hydroxychloroquine 400 mg P.O. BID for five days plus Tab Oseltamivir 75 mg P.O. BID for five days plus Tab Lopinavir-Ritonavir 200/50 mg P.O. two tablets BID for five days plus Tocilizumab (Actemra) 400 mg I.V infusion as a single dose

##### **Category**

Treatment - Drugs

### **Recruitment centers**

#### 1

##### **Recruitment center**

###### **Name of recruitment center**

Masih Daneshvari Hospital

###### **Full name of responsible person**

Farzaneh Dastan

###### **Street address**

Daraabad, Shahid Bahonar St. (Niavaran), Masih Daneshvari Hospital

###### **City**

Tehran

###### **Province**

Tehran

###### **Postal code**

1956944413

###### **Phone**

+98 21 2712 3000

###### **Email**

f\_dastan@sbmu.ac.ir

###### **Web page address**

### **Sponsors / Funding sources**

#### 1

##### **Sponsor**

###### **Name of organization / entity**

Shahid Beheshti University of Medical Sciences

###### **Full name of responsible person**

Afshin Zarghi

###### **Street address**

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

###### **City**

Tehran

###### **Province**

Tehran

##### **Postal code**

1983963113

##### **Phone**

+98 21 23871

##### **Email**

mpd@sbmu.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**

Farzaneh Dastan

###### **Position**

Assistant Professor, Clinical Pharmacy Specialist

###### **Latest degree**

Ph.D.

###### **Other areas of specialty/work**

Medical Pharmacy

###### **Street address**

Valieasr St., Intersection of Niyayesh Highway, Shahid Beheshti University of Medical Sciences, Faculty of Pharmacy

###### **City**

Tehran

###### **Province**

Tehran

###### **Postal code**

1991953381

###### **Phone**

+98 21 8820 0118

###### **Fax**

###### **Email**

f\_dastan@sbmu.ac.ir

###### **Web page address**

### **Person responsible for scientific 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**

Dr. Masih Daneshvari Hospital, Daar-Abad, Niavaran

**City**

Tehran

**Province**

Tehran

**Postal code**

19569-44413

**Phone**

+98 21 2712 3000

**Email**

tabarsi@nritld.ac.ir

+98 21 8820 0118

**Email**

alisaffaei.ss@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

**To whom data/document is available**

Researchers working in academic institutions

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

For research purposes

**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**

Ali Saffaei

**Position**

Clinical Pharmacy Resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Medical Pharmacy

**Street address**

Niayesh Highway., Valiasr Ave.

**City**

Tehran

**Province**

Tehran

**Postal code**

1991953381

**Phone**