

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Evaluating the efficacy and safety of Adalimumab in patients with acute respiratory distress syndrome caused by COVID-19

#### Protocol summary

##### Study aim

Evaluating the efficacy and safety of Adalimumab as a treatment option for patients with COVID-19

##### Design

Prospective clinical trial with parallel randomized control and treatment, open-label groups, phase 2 trial on 60 patients. Block randomization was done using online website ([www.sealedenvelope.com/simple-randomiser/v1/lists](http://www.sealedenvelope.com/simple-randomiser/v1/lists)).

##### Settings and conduct

Place of study: Masih Daneshvari Hospital. How to do the study: 60 patients with COVID-19, using block randomization will be divided in to intervention and control group. This is an open-label study.

##### Participants/Inclusion and exclusion criteria

Patients between 18 and 65 years old who have laboratory confirmed COVID-19 (Corona Virus Disease-19) with RT-PCR (Real-Time Polymerase Chain Reaction) or CT scan and are sever or critically ill, are included in the study. Furthermore, patients must have CRP rise two times the normal value and IL-6 above 7 pg/ml. Study exclusion criteria is as follows: acute or chronic renal failure (creatinine rise above 3 mg/dL during the last 48 hours or GFR les than 30 mL/min), liver failure (LFT rise five times the upper limit or three time rise in symptomatic patients or Child Pugh C or D), allergic reaction while injecting adalimumab with severe extravasation or anaphylactic reaction, patient with mild disease.

##### Intervention groups

Patients in treatment group received single dose of adalimumab ampule (CinnoRA, CinnaGen), 40 mg subcutaneously with supportive treatments according to national guideline. Furthermore, patients in control group received supportive care according national guideline.

##### Main outcome variables

Hospital discharge, need for oxygen support, need for mechanical ventilation, and 28 days mortality.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20151227025726N23**

Registration date: **2020-11-10, 1399/08/20**

Registration timing: **retrospective**

Last update: **2020-11-10, 1399/08/20**

Update count: **0**

##### Registration date

2020-11-10, 1399/08/20

##### 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

2020-08-06, 1399/05/16

##### Expected recruitment end date

2020-11-06, 1399/08/16

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

## Scientific title

Evaluating the efficacy and safety of Adalimumab in patients with acute respiratory distress syndrome caused by COVID-19

## Public title

Evaluating the effects of Adalimumab in patients with acute respiratory distress syndrome caused by COVID-19

## 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) or CT scan. Sever or critically ill patients. CRP rise two times the normal value. IL-6 above 7 pg/ml. Signed the consent form

### Exclusion criteria:

Acute or chronic renal failure (creatinine rise above 3 mg/dL during the last 48 hours or GFR less than 30 mL/min) Liver failure (LFT rise five times the upper limit or three time rise in symptomatic patients or Child Pugh C or D) Allergic reaction while injecting adalimumab with severe extravasation or anaphylactic reaction. Patient with mild disease Pregnancy or breastfeeding Patients with IL-6 below 7 pg/ml Patient with latent or active TB or any other active infection History of active peptic ulcer Receiving drugs effective on interleukin or TNF alpha History of malignancy Patient with heart failure

## 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: **60**

## Randomization (investigator's opinion)

Randomized

## Randomization description

Block randomization method was used in this study. Ten blocks including six patients generated with online website ([www.sealedenvelope.com/simple-randomiser/v1/lists](http://www.sealedenvelope.com/simple-randomiser/v1/lists)). In each block, three patients will be assigned to adalimumab group and three 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

2020-08-05, 1399/05/15

#### Ethics committee reference number

IR.SBMU.NRITLD.REC.1399.154

## 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

Clinical improvement (hospital discharge)

#### Timepoint

Daily until discharge

#### Method of measurement

Medical record

### 2

#### Description

Clinical improvement (length of time in which patient needs oxygen therapy)

#### Timepoint

Daily until discharge

#### Method of measurement

Medical record

### 3

#### Description

Need for mechanical ventilation

#### Timepoint

Daily until discharge

#### Method of measurement

Medical record

## 4

### **Description**

28 days mortality

### **Timepoint**

From the first day of admission until 28 days

### **Method of measurement**

Medical record

## **Secondary outcomes**

## 1

### **Description**

Number of days admitted to critical care unit

### **Timepoint**

Daily until discharge

### **Method of measurement**

Medical record

## 2

### **Description**

Length of hospital stay

### **Timepoint**

Daily until discharge

### **Method of measurement**

Medical record

## 3

### **Description**

Lung radiological changes

### **Timepoint**

First day of the study then at day 5

### **Method of measurement**

Computed tomography

## 4

### **Description**

RT-PCR result

### **Timepoint**

First day of the study then at day 5

### **Method of measurement**

Medical record

## **Intervention groups**

## 1

### **Description**

Intervention group: Patients in treatment group received single dose of adalimumab ampule (CinnoRA, CinnaGen), 40 mg subcutaneously with supportive treatments according to national guideline. Supportive treatment includes interferon b1a (Resigen) 44 microgram every other day for 3 doses + Lopinavir/Ritonavir 200-50 mg (Hetero Labs Limited) 2 Tab twice daily for 7 days.

### **Category**

Treatment - Drugs

## 2

### **Description**

Control group: Patients in control group received supportive care according national guideline. Supportive treatment includes interferon b1a (Resigen) 44 microgram every other day for 3 doses + 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**

Farzaneh Dastan

#### **Street address**

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

#### **City**

Tehran

#### **Province**

Tehran

#### **Postal code**

1956944413

#### **Phone**

+98 21 2712 3000

#### **Email**

f\_dastan@sbmu.ac.ir

## **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

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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**

Atefeh Fakharian

**Position**

Associate professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Internal Medicine

**Street address**

Dr. Masih Daneshvari Hospital, Daar-Abad, Niavaran

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Atefeh.fakharian7@gmail.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

**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, Valieasr St.

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**Email**

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**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

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**Province**

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**Postal code**

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**Phone**

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**Email**

z.mirshafiei@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 through Email  
(fzh.dastan@gmail.com).

**Comments**