

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

23 Feb 2026

### Evolution of the efficacy and safety of Dexamethasone administration in patients with mild to moderate COVID-19 acute respiratory disease syndrome

#### Protocol summary

##### Study aim

Studying the therapeutic effect and side effects of dexamethasone in COVID-19 positive patients with mild to moderate symptoms

##### Design

Clinical trial with parallel randomized groups

##### Settings and conduct

This is a randomized clinical trial which will be done at Dr. Masih Daneshvari Hospital

##### Participants/Inclusion and exclusion criteria

In this study, 18 year old patients with confirmed COVID-19 through RT-PCR, who signed consent form, were included in the study. Furthermore, patients with  $PiO_2/FiO_2$  between 100 and 300 mmHg, and bilateral lung infiltration with mild to moderate symptoms were included. Patients with acute and chronic renal disease, liver disease, hyperglycemia, with sever symptoms were excluded from this study.

##### Intervention groups

Patients in treatment group received dexamethasone (manufactured by Abouraihan Pharmaceutical Company) 20 mg intravenously from day one to 5 then 10 mg for days 6 to 10. patients in control group did not receive dexamethasone. patients in both groups received oxygen, fluid support, and lopinavir/ritonavir 200/50 mg to Tab BID as standard therapy.

##### Main outcome variables

Need of mechanical ventilation and death

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20151227025726N17**

Registration date: **2020-05-31, 1399/03/11**

Registration timing: **retrospective**

Last update: **2020-05-31, 1399/03/11**

Update count: **0**

##### Registration date

2020-05-31, 1399/03/11

##### 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

2020-04-24, 1399/02/05

##### Expected recruitment end date

2020-05-25, 1399/03/05

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Evolution of the efficacy and safety of Dexamethasone administration in patients with mild to moderate COVID-19 acute respiratory disease syndrome

##### Public title

Evolution of the efficacy and safety of Dexamethasone administration in COVID-19

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

Patients between 18 and 65 years old Laboratory COVID-19 confirmed with RT-PCR Mild to moderately ill patients Patients with PaO<sub>2</sub>/FiO<sub>2</sub> between 100-300 Signed the consent form

### Exclusion criteria:

Acute or chronic renal impairment (Creatinin rise more than 3 units in the last 48 hours and/or GFR less than 30 mL/min) Chronic liver disease (Rise in LFTs more than 5 times and/or 3 times rise in LFTs in symptomatic patients and/or Child pugh C,D) Allergy to corticosteroids while being injected with extravasation and signs of anaphylactic shock. Patients with hyperglycemia Pregnancy and lactation

## Age

From **18 years** old

## Gender

Both

## Phase

2-3

## Groups that have been masked

*No information*

## Sample size

Target sample size: **48**

## Randomization (investigator's opinion)

Randomized

## Randomization description

Block randomization method was used in this study. 12 blocks including 4 patients generated with online website ([www.sealedenvelope.com](http://www.sealedenvelope.com)). In each block, two patients will be assigned to Dexamethasone group and two 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

Vice-Chancellor in Research Affairs - 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

2020-04-22, 1399/02/03

##### Ethics committee reference number

IR.SBMU.NRITLD.REC.1399.071

## 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 invasive mechanical ventilation

#### Timepoint

Daily

#### Method of measurement

Medical record

### 2

#### Description

Death

#### Timepoint

At the end of the study

#### Method of measurement

Medical record

## Secondary outcomes

### 1

#### Description

Weaning from oxygen support

#### Timepoint

Daily

#### Method of measurement

Medical record

### 2

#### Description

Length of hospital stay

#### Timepoint

At the end of the study

#### Method of measurement

Medical record

### 3

#### Description

Lung radiology changes

### Timepoint

At admission time and seven and 14 days later

### Method of measurement

At admission time and seven and 14 days later

## Intervention groups

### 1

#### Description

Intervention group: Patients in dexamethasone group receive intravenous dexamethasone (manufactured by Abouraihan Pharmaceutical Company) at dose of 20 mg/day for day's one to five and then 10 mg/day for day's 6 to 10. Also patients receive supportive treatments including oxygen therapy and fluid therapy. According to the national guideline, patients receive Lopinavir/ritonavir tablets (Hetered Pharmaceutical Company, India) at dose of 200/50 mg in two tablets per day.

#### Category

Treatment - Drugs

### 2

#### Description

Control group: Patients receive supportive treatments including oxygen therapy and fluid therapy. Also, according to the national guideline, patients receive Lopinavir/ritonavir tablets (Hetered Pharmaceutical Company, India) at dose of 200/50 mg in two tablets per day.

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Masih Daneshvari Hospital

##### Full name of responsible person

Payam Tabarsi

##### Street address

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

##### City

Tehran

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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

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##### Phone

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##### 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

Seyed Mohammadreza Hashemian

##### Position

Professor

##### Latest degree

Subspecialist

##### Other areas of specialty/work

Others

##### Street address

Dr. Masih Daneshvari Hospital, Daar-Abad, Niavaran

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## 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

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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

**Street address**

Dr. Masih Daneshvari Hospital, Daar-Abad, Niavaran

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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

**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**

Researchers can meet Dr. farzaneh Dastan at Dr. Masih Daneshvari Hospital, Daar-Abad, Niavaran or request data via email: fzh.dastan@gmail.com

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

Official letter to the researchers

**Comments**