

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 2026

### Evaluation of the Safety and Efficacy of Sofosbuvir in patients with moderate COVID19, A Single-blind, randomized controlled trial

#### Protocol summary

##### Study aim

Evaluation of the Safety and Efficacy of Sofosbuvir in patients with moderate COVID19, A randomized and Single-blind clinical trial

##### Design

a single-blind randomized controlled study with two parallel arms with 50 patients in each.

##### Settings and conduct

The study will be conducted at Shohada Hospital. Patients will be randomly assigned to the national protocol with or without sofosbuvir in two parallel groups. Study outcomes will be evaluated over a one-month period. Patients and outcome assessors will be blind using the random codes.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Both genders, aging from 18 to 80 Y.O. who are admitted in hospital, showing at least one of these criteria: Fever (Oral temperature  $\geq 38^{\circ}\text{C}$ ), Respiratory rate  $>24/\text{min}$ ,  $\text{O}_2\text{Sat} < 93\%$  in room air or the  $\text{PaO}_2/\text{FiO}_2$  ratio  $\leq 300\text{mgHg}$ , Laboratory (RT-PCR) confirming the infection with 2019-Covid Virus, Lung involvement in CT-Scan less than 50% (in compliance with the involvement of moderate COVID19),  $5 \leq \text{days}$  since onset of the COVID19 symptoms  $\leq 10$  Exclusion criteria: History of allergic reaction to the drugs used in this clinical trial in a pregnancy or breast feeding status, test Receipt of any experimental treatment for COVID-19 before hand, Heart rate  $< 60/\text{min}$ , currently on amiodarone prescription, presence of multi organ failure evidence, in need of mechanical ventilation, estimated glomerular filtration rate  $< 50 \text{ mL}/1.73 \text{ m}^2/\text{min}$ , admitted in ICU ward, who are in shock

##### Intervention groups

50 patients admitted in COVID ward from 3/4/2021 with definitive diagnosis of moderate COVID19. For one arm (50 patients) the treatment regimen will consist of interferon+sofosbuvir+national protocol for COVID19 and for the other arm (50 patients) it will be interferion+national protocol for COVID19

##### Main outcome variables

Duration of remission, by length of stay and discharge (if recovery happens)/death

#### General information

##### Reason for update

اصلاح نحوه کورسازی در مطالعه از دوسر کور به یک سر کور

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20180302038915N1**

Registration date: **2021-04-05, 1400/01/16**

Registration timing: **prospective**

Last update: **2022-04-29, 1401/02/09**

Update count: **1**

##### Registration date

2021-04-05, 1400/01/16

##### Registrant information

###### Name

Rama Bozorgmehr

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 2271 8001

###### Email address

r.bozorgmehr@sbm.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2021-04-14, 1400/01/25

##### Expected recruitment end date

2021-09-16, 1400/06/25

##### Actual recruitment start date

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Evaluation of the Safety and Efficacy of Sofosbuvir in patients with moderate COVID19, A Single-blind, randomized controlled trial

**Public title**

Safety and efficacy of sofosbuvir in the moderate COVID19

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Both genders Age ranging from 18 to 80 Y.O. who are admitted in hospital showing at least one of these criteria: Fever (Oral temperature  $\geq 38$  °C) , Respiratory rate  $>24$ /min , O<sub>2</sub>Sat $<93\%$  in room air or the PaO<sub>2</sub>/FiO<sub>2</sub> ratio  $\leq 300$ mgHg Laboratory (RT-PCR) confirming the infection with 2019-Covid Virus Lung involvement in CT-Scan less than 50 % ( in compliance with the involvement of moderate COVID19 ) 5  $\leq$ days since onset of the COVID19 symptoms  $\leq 10$

**Exclusion criteria:**

History of allergic reaction to the drugs used in this clinical trial in a pregnancy or breast feeding status test Receipt of any experimental treatment for COVID-19 before hand Heart rate  $< 60$ /min currently on amiodarone prescription presence of multi organ failure evidence in need of mechanical ventilation estimated glomerular filtration rate  $< 50$  mL/1.73 m<sup>2</sup>/min admitted in ICU ward who are in shock

**Age**

From **18 years** old to **80 years** old

**Gender**

Both

**Phase**

3

**Groups that have been masked**

- Care provider
- Investigator
- Outcome assessor

**Sample size**

Target sample size: **50**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

by block randomization technique , allocation of the patients will be completely randomized via using a software. there will be 2 arms

**Blinding (investigator's opinion)**

Single blinded

**Blinding description**

This study will be Single- blinded. Care providers and data analyzers will be blind.

**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**

Aarabi st , Evin

**City**

Tehran

**Province**

Tehran

**Postal code**

1985717434

**Approval date**

2021-02-21, 1399/12/03

**Ethics committee reference number**

IR.SBMU.RETECH.REC1399.1322

**Health conditions studied****1****Description of health condition studied**

COVID19

**ICD-10 code**

U07.1

**ICD-10 code description**

Coronavirus infection, unspecified

**Primary outcomes****1****Description**

Time to reach clinical recovery

**Timepoint**

after 10 days on treatment initiation

**Method of measurement**

daily physical exam, assessing vanishing of tachypnea ,blood saturation of O<sub>2</sub>(using pulse-oximeter) , fever( using thermometer)

**Secondary outcomes****1****Description**

The rate of patients who need to admit in ICU ward

**Timepoint**

14 days after Treatment initiation

**Method of measurement**

physical exam and paraclinical evaluation

## 2

### **Description**

The rate of patient expiry in each arm

### **Timepoint**

14 days after treatment initiation

### **Method of measurement**

questionnaire

## 3

### **Description**

remission of clinical symptoms in each arm

### **Timepoint**

14 days after treatment initiation

### **Method of measurement**

physical exam ( thermometer and pulse-oximeter)

## **Intervention groups**

### 1

#### **Description**

Intervention group: all the patients are required to fill the consent form to be able to enter the trial. 50 patients admitted in the COVID ward with definitive moderate COVID19 diagnosis and randomly divided into two arms( each with 50 patients). in the intervention arm, the treatment regimen will consist of sofosbuvir, interferon beta 1a, and national protocol for COVID treatment. interferon beta 1a 44 micrograms will be administered subcutaneously 3-5 doses a day and sofosbuvir 400 mg orally and daily for 10 days and paraclinical tests and vital signs and blood O2 saturation will be assessed according to the plan by experienced health providers

#### **Category**

Treatment - Drugs

### 2

#### **Description**

Control group: All the patients are required to fill the consent form to be able to enter the trial. 50 patients admitted to the COVID ward with definitive moderate COVID19 diagnosis and randomly divided into two arms( each with 50 patients). in the intervention arm, the treatment regimen will consist of interferon beta 1a and national protocol for COVID treatment. interferon beta 1a 44 micrograms will be administered subcutaneously 3-5 doses a day for 10 days and paraclinical tests and vital signs and blood O2 saturation will be assessed according to the plan by experienced health providers

#### **Category**

Treatment - Drugs

## **Recruitment centers**

### 1

#### **Recruitment center**

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

Shohada-e-Tajrish hospital

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

Rama Bozorgmehr

#### **Street address**

Shahrdari Aven. , Tajrish Square

#### **City**

Tehran

#### **Province**

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#### **Postal code**

1989934148

#### **Phone**

+98 21 25719

#### **Email**

pr\_shohada@sbm.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**

Shahid Beheshti University of Medical Sciences, Headquarters Building 2, Floor 5, Research and Technology Department

##### **City**

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##### **Postal code**

1985717443

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##### **Email**

Mpajouhesh@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**

Fariba Ghorbani

**Position**

Researcher, MD, PhD

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Medical Biotechnology

**Street address**

Dr, Masih Daneshvary Hospital, Niavaraan,  
Daaraabaad,

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dr.f.ghorbani@gmail.com

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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**

Farbod Amiri

**Position**

Medical Intern

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Orthopedics

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farbod\_am@sbmu.ac.ir

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

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Rama Bozorgmehr

**Position**

Assistant professor of pulmonology and critical care  
medicine

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Internal Medicine

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Shohada Hospital, Shahrdari Aven, Tajrish square

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**Province**

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**Postal code**

1989934148

**Phone**

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**Fax****Email****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