# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

09 Jun 2026

## Efficacy and safety of Sofosbuvir in the treatment of SARS-CoV-2: An Open Label phase II Trial

### Protocol summary

**Study aim**

Determination of efficacy and safety of Sofosbuvir in the treatment of SARS-CoV-2

**Design**

Clinical trial phase II Allocation: Randomized Intervention Model: Parallel Assignment Masking: None (Open Label) Primary Purpose: Treatment Estimated Enrollment: 30 in each arm

**Settings and conduct**

Imam Hossein Hospital affliated to Shahid Beheshti University of Medical Sciences. Volunteers will be randomly assigned into two intervention groups (A and B) and will be admitted according to the study protocol. Medical Care will be provided by physicians . Blindness will be done to the principle investigator of the study as well as the statistical analyzer

**Participants/Inclusion and exclusion criteria**

Inclusion Criteria: Written informed consent; SARS-CoV)-2 infection confirmed by PCR test ≤ 4 days before randomization; Currently hospitalized with fever; SpO2<94%; Radiographic evidence of pulmonary infiltrates Exclusion Criteria: Participation in any other clinical trial of an experimental trial for COVID-19 History of taking other antivirals aginst COVID-19 in the last 24 hours at the enrollment in the study Multi-organ failure Need mechanical ventilation at screening Liver enzymes>5 upper limit Normal GFR< 30 mL/min Concurrent treatment with other agents with potential important drug interaction with Sofosbuvir Pregnant woman or man who his spouse is pregnant

**Intervention groups**

Group´A: Experimental: Participants will receive standard of care therapy continued together with Sofosbuvir 400 mg single dose daily for 5 days Group B: Experimental: Participants will receive standard of care therapy continued together with Sofosbuvir 400 mg single dose daily for 10 days

**Main outcome variables**

Normalization of fever( ≤37.2 °C oral, or ≤36.6 °C armpit, or ≤37.8 °C rectal AND oxygen saturation (≥94% on room air), sustained for at least 72 hours within 14 days from initiation of Trial.

### General information

**Reason for update**

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT20200328046882N1**
Registration date: **2020-04-05, 1399/01/17**
Registration timing: **registered_while_recruiting**

Last update: **2020-04-05, 1399/01/17**
Update count: **0**

**Registration date**

2020-04-05, 1399/01/17

**Registrant information**

**Name**

Mostafa Alavi -Moghaddam

**Name of organization / entity**

**Country**

Iran (Islamic Republic of)

**Phone**

+98 21 7754 3634

**Email address**

mosalavi@sbmu.ac.ir

**Recruitment status**

**Recruitment complete**

**Funding source**

**Expected recruitment start date**

2020-04-04, 1399/01/16

**Expected recruitment end date**

2020-07-06, 1399/04/16

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Efficacy and safety of Sofosbuvir in the treatment of SARS-CoV-2: An Open Label phase II Trial

**Public title**

Efficacy and safety of Sofosbuvir in the treatment of SARS-CoV-2: An Open Label phase II Trial

**Purpose**

Treatment

**Inclusion/Exclusion criteria**

**Inclusion criteria:**

Written informed consent prior to performing study procedures (SARS-CoV)-2 infection confirmed (PCR) test ≤ 4 days before randomization Currently hospitalized with fever Peripheral capillary oxygen saturation (SpO2) ≤ 94% on room air at screening Radiographic evidence of pulmonary infiltrates

**Exclusion criteria:**

Participation in any other clinical trial of an experimental treatment for COVID-19 Concurrent treatment with other agents with actual or possible direct acting antiviral activity against SARS-CoV-2 is prohibited < 24 hours prior to study drug dosing Evidence of multi-organ failure Requiring mechanical ventilation at screening Alanine Aminotransferase (ALT) or aspartate aminotransferase (AST) > 5 X upper limit of normal (ULN) Creatinine clearance <30mL/min pregnant woman or man who his spouse is pregnant Coadministration of amiodarone, HIV Protease Inhibitors, rifabutin or rifapentine , phenobarbital or oxcarbazepine

**Age**

From **18 years** old

**Gender**

Both

**Phase**

2

**Groups that have been masked**

- Participant
- Investigator
- Outcome assessor

**Sample size**

Target sample size: **60**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Allocation of patients in the study arms will be done by using table of random numbers, without concealment

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

Allocation of the patients in to groups A or B will be randomized. Physicians who involve in the care of the patients will not be blinded. Principle Investigator who will assess the outcomes and the statistician who will analyze the data all will be blinded.

**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**

5th Floor, Bldg No 2, Shahid Beheshti Medical Sciences University Arabi Ave,Velenjak Tehran ,IRAN

**City**

Tehran

**Province**

Tehran

**Postal code**

19839-63113

**Approval date**

2020-03-28, 1399/01/09

**Ethics committee reference number**

IR.SBMU.RETECH.REC.1399.001

## Health conditions studied

### 1

**Description of health condition studied**

SARS-CoV-2 ãssociated SARI

**ICD-10 code**

U07.1

**ICD-10 code description**

SARS-CoV-2

## Primary outcomes

### 1

**Description**

Temperature( < 36.6 °C armpit, or < 37.2 °C oral, ) without using antipyretic drugs sustained for at least 72 hours

**Timepoint**

During 14 days after enrollment in the study

**Method of measurement**

Digital Thermometer

### 2

**Description**

Spo2>= 94% (at room air) sustained for at least 72 hours without Oxygen therapy

**Timepoint**

During 14 days after enrollment in the study

**Method of measurement**

Pulse Oximeter

## Secondary outcomes

### 1

**Description**
All causes mortality
**Timepoint**
During 14 days after enrollment in the study
**Method of measurement**
As defined in ACLS protocol

### 2

**Description**
Length of stay in hospital
**Timepoint**
Time duration between admission date and discharge date
**Method of measurement**
Calculation

### 3

**Description**
Transfer to ICU due to need of mechanical ventilation
**Timepoint**
During 14 days after enrollment in the study
**Method of measurement**
Patient Chart review

### 4

**Description**
Report of Sofosbuvir adverse reactions need to stop the treatment
**Timepoint**
During 14 days after enrollment in the study
**Method of measurement**
physician judgement

## Intervention groups

### 1

**Description**
Intervention group : Sofosbuvir 400mg OD for 5 days+ standard treatment
**Category**
Treatment - Drugs

### 2

**Description**
Intervention group: Sofosbuvir 400mg OD for 10 days+ standard treatment
**Category**
Treatment - Drugs

## Recruitment centers

### 1

**Recruitment center**
**Name of recruitment center**
Clinical Research Development Center-Imam Hossein Hospital affliated to Shahid Beheshti University o
**Full name of responsible person**
Mostafa Alavi-Moghaddam
**Street address**
Clinical Research Development Center, Imam Hossein Hospital, Shahid Madani Ave.
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mosalavi@sbmu.ac.ir
**Web page address**
https://ehcrdc.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**
5th floor,Bldg No 2, Ŝhahid Beheshti University of Medical Sciences, Arabi Ave.,Daneshjoo Blvd, Velenjak, Tehran, IRAN
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19839-63113
**Phone**
+98 21 2243 9780
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+98 21 2243 9981
**Email**
zarghi@sbmu.ac.ir
**Web page address**
https://research.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**
Mostafa Alavi-Moghaddam
**Position**
Associate professor
**Latest degree**
Subspecialist
**Other areas of specialty/work**
Infectious diseases
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## Person responsible for scientific inquiries

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## Person responsible for updating data

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## 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**
No - There is not a plan to make this available
**Statistical Analysis Plan**
No - There is not a plan to make this available
**Informed Consent Form**
No - There is not a plan to make this available
**Clinical Study Report**
No - There is not a plan to make this available
**Analytic Code**
No - There is not a plan to make this available
**Data Dictionary**
No - There is not a plan to make this available