Clinical Trial Protocol
Iranian Registry of Clinical Trials

02 Nov 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
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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
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Fax
+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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Web page address
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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