

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Sep 2026

### A prospective randomized controlled trial comparing Sovodak (Sofosbuvir plus Daclatasvir) in participants with moderate to severe Coronavirus disease (COVID-19) compared to standard of care treatment

#### Protocol summary

##### Study aim

To evaluate whether Sovodak (Sofosbuvir plus Daclatasvir) increases significant clinical improvement as compared to standard of care in hospitalized patients with moderate to severe COVID-19.

##### Design

This is a parallel 2-arm randomized, controlled, double-blind, multi center study. 70 patients are enrolled and followed for 14 days.

##### Settings and conduct

The study will be conducted in Shariati hospital (Tehran), Baharloo (Tehran), Sina (Tehran), Sayyad Shirazi (Gorgan) by investigators of digestive disease research institute (TUMS). Radiologists, physicians who assess outcomes and the statistician analyzing the data will be blinded but the patients and physicians who treat patients will know the assigned treatment group.

##### Participants/Inclusion and exclusion criteria

All moderate to severe COVID-19 infected patients admitted to Shariati hospital (Tehran), Baharloo (Tehran), Sina (Tehran), Sayyad Shirazi (Gorgan) Inclusion criteria: age  $\geq 18$ y; hospitalized patients with: Fever (Oral temperature  $\geq 37.8$  °C) and at least one of Respiratory rate  $>24/\text{min}$  /  $\text{O}_2\text{Sat} < 94\%$  or the  $\text{PaO}_2/\text{FiO}_2$  ratio  $< 300\text{mgHg}$ ; PCR confirmed; diagnostic chest CT scan. Exclusion criteria: known allergic reaction to intervention drug, pregnant or breastfeeding, any prior experimental treatment for COVID-19, heart rate  $< 60/\text{min}$ , taking Amiodarone, evidence of multiorgan failure, requiring mechanical ventilation at screening,  $\text{eGFR} < 50 \text{ mL/min}$

##### Intervention groups

70 eligible patients with moderate to severe COVID-19 in a 1:1 ratio: • Standard of care treatment • Sovodak tablet (Sofosbuvir 400mg/Daclatasvir 60mg) + Standard of care treatment

##### Main outcome variables

Clinical recovery (composite) within 14 days from

initiation of study treatment until normalization of fever ( $\leq 37.2$  °C oral), respiratory rate ( $\leq 24/\text{minute}$  on room air), and oxygen saturation ( $\geq 94\%$  on room air), sustained for at least 24 hours.

#### General information

##### Reason for update

The trial was completed.

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20200128046294N2**

Registration date: **2020-03-14, 1398/12/24**

Registration timing: **prospective**

Last update: **2020-06-01, 1399/03/12**

Update count: **4**

##### Registration date

2020-03-14, 1398/12/24

##### Registrant information

###### Name

Anahita Sadeghi

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 8241 5104

###### Email address

a-sadeghi@tums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-03-26, 1399/01/07

##### Expected recruitment end date

2020-06-20, 1399/03/31

**Actual recruitment start date**

2020-03-26, 1399/01/07

**Actual recruitment end date**

2020-04-26, 1399/02/07

**Trial completion date**

2020-05-18, 1399/02/29

**Scientific title**

A prospective randomized controlled trial comparing Sovodak (Sofosbuvir plus Daclatasvir) in participants with moderate to severe Coronavirus disease (COVID-19) compared to standard of care treatment

**Public title**

Study to Evaluate the Safety and Efficacy of Sofosbuvir/Daclatasvir in Participants with Moderate to Severe Coronavirus Disease (COVID-19)

**Purpose**

Treatment

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

Both genders Age  $\geq 18$  years at time of signing Informed Consent Form Willing and able to provide written informed consent prior to performing study to any assigned treatment arm Must agree not to enroll in another study of an investigational agent prior to completion of study Will be admitted to Shariati hospital (Tehran), Baharloo (Tehran), Sina (Tehran), Sayyad Shirazi (Gorgan) and not transferred to another hospital Laboratory (RT-PCR) confirmed infection with 2019-nCoV Lung involvement confirmed with chest CT scan Hospitalized patients with: Fever (Oral temperature  $\geq 37.8$  °C) and at least one of Respiratory rate  $>24/\text{min}$  /  $\text{O}_2\text{Sat} < 94\%$  or the  $\text{PaO}_2/\text{FiO}_2$  ratio  $< 300\text{mgHg}$   $\leq 8$  days since illness onset

**Exclusion criteria:**

Known allergic reaction to Sofosbuvir or Daclatasvir Pregnant or breastfeeding, or positive pregnancy test Receipt of any experimental treatment for COVID-19 prior to the time of the screening evaluation Heart rate  $< 60/\text{min}$  Taking Amiodarone Evidence of multiorgan failure Requiring mechanical ventilation at screening  $\text{eGFR} < 50 \text{ mL/min}$

**Age**

From 18 years old

**Gender**

Both

**Phase**

3

**Groups that have been masked**

- Investigator
- Outcome assessor
- Data analyser

**Sample size**

Target sample size: 70

Actual sample size reached: 70

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Patients will be randomized in a 1:1 ratio into one of the treatment groups and standard of care group using

computer generated randomization plan. The date and time of randomization will be recorded. Allocation concealment will be done with the sealed envelope method.

**Blinding (investigator's opinion)**

Single blinded

**Blinding description**

The treatment assignment will remain unknown until the patient is randomized. Physicians who treat patients and the patients will not be blinded. Radiologists, physicians who assess outcomes and the statistician analyzing 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**

Institutional Research Ethics Committee, Vice-Chancellor in Research Affairs- Tehran University of M

**Street address**

Central Building of Tehran University of Medical Sciences: No. 226, Qods St., Keshavarz Blvd., Tehran, Iran

**City**

Tehran

**Province**

Tehran

**Postal code**

1416753955

**Approval date**

2020-03-11, 1398/12/21

**Ethics committee reference number**

IR.TUMS.VCR.REC.1398.1035

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

COVID-19

**ICD-10 code**

U07.1

**ICD-10 code description**

COVID-19

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

Clinical recovery (composite) within 14 days from

initiation of study treatment until normalization of fever ( $\leq 37.2$  °C oral), respiratory rate ( $\leq 24$ /minute on room air), and oxygen saturation ( $\geq 94\%$  on room air), sustained for at least 24 hours.

**Timepoint**

daily up to 14 days after starting the trial

**Method of measurement**

Clinical examination

## Secondary outcomes

### 1

**Description**

Requirement for mechanical ventilation

**Timepoint**

daily up to day 14

**Method of measurement**

Clinical evaluation

### 2

**Description**

Radiological changes

**Timepoint**

day 14 or sooner at the discretion of the physician

**Method of measurement**

Chest CT scan

### 3

**Description**

Serious adverse events

**Timepoint**

Any time during study up to day 14

**Method of measurement**

Clinical evaluation

### 4

**Description**

All-cause mortality

**Timepoint**

Any time during study up to day 14

**Method of measurement**

Clinical evaluation

## Intervention groups

### 1

**Description**

Control group: Standard of care treatment according to the national guidelines for the treatment of COVID-19

**Category**

Treatment - Drugs

### 2

**Description**

Intervention group: Sovodak, Company: Rojan, Daily single oral tablet containing 400mg of Sofosbovir and

60mg of Daclatasvir plus Standard of care treatment

**Category**

Treatment - Drugs

## Recruitment centers

### 1

**Recruitment center****Name of recruitment center**

Shariati Hospital

**Full name of responsible person**

Dr Anahita Sadeghi

**Street address**

Shariati Hospital, North Kargar Street, Tehran

**City**

Tehran

**Province**

Tehran

**Postal code**

1411713135

**Phone**

+98 21 8241 5000

**Fax**

+98 21 8241 5400

**Email**

a-sadeghi@tums.ac.ir

**Web page address**

### 2

**Recruitment center****Name of recruitment center**

Sina Hospital

**Full name of responsible person**

Mahnaz Montazeri

**Street address**

Sina Hospital, Hassan Abad Square, Imam Khomeini Ave, Tehran, Iran

**City**

Tehran

**Province**

Tehran

**Postal code**

1136746911

**Phone**

+98 21 6634 8500

**Email**

mahnazmontazeri@yahoo.com

### 3

**Recruitment center****Name of recruitment center**

Baharloo hospital

**Full name of responsible person**

Hadiseh Hosemi Roudsari

**Street address**

Baharloo Hospital - Behdari.street - Railway.square

**City**

Tehran

**Province**

Tehran  
**Postal code**  
1339973111  
**Phone**  
+98 21 5565 8500  
**Email**  
h-hosami@tums.ac.ir  
**Web page address**

#### 4

##### **Recruitment center**

**Name of recruitment center**  
Sayad Shirazi Hospital  
**Full name of responsible person**  
Alireza Norouzi  
**Street address**  
Shahid Sayyad Shirazi Boulevard  
**City**  
Gorgan  
**Province**  
Golestan  
**Postal code**  
4917867439  
**Phone**  
+98 17 3226 1175  
**Email**  
norouzi54@gmail.com

## **Sponsors / Funding sources**

#### 1

##### **Sponsor**

**Name of organization / entity**  
Digestive Disease Research Institute  
**Full name of responsible person**  
Dr Anahita Sadeghi  
**Street address**  
Digestive Disease Research Institute, Shariati  
Hospital, Kargar Street, Tehran  
**City**  
Tehran  
**Province**  
Tehran  
**Postal code**  
1411713135  
**Phone**  
+98 21 8241 5000  
**Fax**  
+98 21 8241 5400  
**Email**  
info@ddri.ir  
**Web page address**  
<https://ddri.ir/>

##### **Grant name**

##### **Grant code / Reference number**

**Is the source of funding the same sponsor organization/entity?**  
Yes

##### **Title of funding source**

Digestive Disease Research Institute

##### **Proportion provided by this source**

50

##### **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

#### 2

##### **Sponsor**

##### **Name of organization / entity**

Fannavarar Rojan Mohaghegh Daru

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

Fannavarar Rojan Mohaghegh Daru

##### **Street address**

Number 10, block 8, Hamedan Street, North Kargar  
Street, Tehran

##### **City**

Tehran

##### **Province**

Tehran

##### **Postal code**

1418693918

##### **Phone**

+98 21 6658 2689

##### **Fax**

+98 21 6658 2689

##### **Email**

info@rojanpharma.com

##### **Web page address**

<https://sovodak.com/>

##### **Grant name**

##### **Grant code / Reference number**

**Is the source of funding the same sponsor organization/entity?**

Yes

##### **Title of funding source**

Fannavarar Rojan Mohaghegh Daru

##### **Proportion provided by this source**

50

##### **Public or private sector**

Private

##### **Domestic or foreign origin**

Domestic

##### **Category of foreign source of funding**

empty

##### **Country of origin**

##### **Type of organization providing the funding**

Industry

## **Person responsible for general inquiries**

##### **Contact**

##### **Name of organization / entity**

Tehran University of Medical Sciences

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

Dr Hossein Poustchi

**Position**  
Associate Professor  
**Latest degree**  
Specialist  
**Other areas of specialty/work**  
Epidemiology  
**Street address**  
Shariati Hospital, Kargar Street, Tehran  
**City**  
Tehran  
**Province**  
Tehran  
**Postal code**  
1411713135  
**Phone**  
+98 21 8241 5000  
**Email**  
h.poustchi@gmail.com

## Person responsible for scientific inquiries

**Contact**  
**Name of organization / entity**  
Tehran University of Medical Sciences  
**Full name of responsible person**  
Shirin Afhami  
**Position**  
Associate Professor  
**Latest degree**  
Specialist  
**Other areas of specialty/work**  
Infectious diseases  
**Street address**  
Shariati Hospital, Kargar Street, Tehran  
**City**  
Tehran  
**Province**  
Tehran  
**Postal code**  
1411713135  
**Phone**  
+98 21 8490 2557  
**Email**  
afhamish@tums.ac.ir

## Person responsible for updating data

**Contact**  
**Name of organization / entity**  
Tehran University of Medical Sciences  
**Full name of responsible person**  
Dr Anahita Sadeghi  
**Position**

Assistant Professor  
**Latest degree**  
Subspecialist  
**Other areas of specialty/work**  
Internal Medicine  
**Street address**  
Shariati Hospital, Kargar Street, Tehran  
**City**  
Tehran  
**Province**  
Tehran  
**Postal code**  
1411713135  
**Phone**  
+98 21 8241 5176  
**Email**  
anahita825@gmail.com

## 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**  
Yes - There is a plan to make this available  
**Statistical Analysis Plan**  
Yes - There is a plan to make this available  
**Informed Consent Form**  
Yes - There is 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**  
Not applicable  
**Data Dictionary**  
Not applicable  
**Title and more details about the data/document**  
The study protocol, statistical analytic plan informed consent forms will be shared as supplementary material at the time of publication of results.  
**When the data will become available and for how long**  
At the time of publication  
**To whom data/document is available**  
Will be publically available as a supplement accompanying the published article.  
**Under which criteria data/document could be used**  
To interpret the findings of published study, and to use as a reference for future research  
**From where data/document is obtainable**  
On the website of journal that will publish the research  
**What processes are involved for a request to access data/document**  
They will be publically available.  
**Comments**