

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### A Multicentre, Quadruple-blind, Randomized, Parallel-group Study to Compare the Efficacy of Sofosbuvir and Daclatasvir vs. Placebo in the Outpatient Treatment of COVID-19 in adults

#### Protocol summary

##### Study aim

To compare the rate of treatment failure between sofosbuvir daclatasvir and placebo in ambulatory patients with COVID-19

##### Design

Randomized, placebo-controlled, quadruple blind multicentre superiority trial with two parallel groups and primary endpoints of hospitalization during 14 days or all-cause mortality with 1:1 allocation ratio.

##### Settings and conduct

Patients will be recruited from urban community clinics designated for COVID-19 patients according to the national protocols of the ministry of health in Iran.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: adult patients ( $\geq 18$  years) must comply with all of the following: 1. Onset of symptoms within 7 days before presentation: fever, cough, chest discomfort, dyspnea, loss of taste or smell, severe body aches, weakness or fatigue 2. Laboratory-confirmed SARS-CoV-2 infection by qualitative Reverse transcription polymerase chain reaction (RT-PCR) 3. Able to provide written, informed consent 4. Able to comply with study protocol for follow-up 5. Not requiring hospitalization at the time of recruitment Exclusion criteria: 1. Personal history of COVID-19 2. Pregnancy or breastfeeding 3. Known severe chronic kidney disease requiring dialysis or eGFR  $< 30$  4. Taking medications that interfere with trial drugs including amiodarone or warfarin 5. Heart rate  $< 50$  / min 6. Receipt of any experimental treatment for SARS-CoV-2 (off-label, compassionate use, or trial related) within the 30 days prior to the time of the screening evaluation

##### Intervention groups

A single daily tablet containing sofosbuvir 400mg and daclatasvir 60mg (Sovodak, Fanavarzan Rojan Mohaghegh Daru Co., Tehran, Iran) OR placebo for 10 days.

##### Main outcome variables

Difference between the two treatment arms in the proportion of participants classed as treatment failure (need for hospital admission or all-cause mortality) at 14 days from enrolment.

#### General information

##### Reason for update

##### Acronym

SODACAN

##### IRCT registration information

IRCT registration number: **IRCT20200831048568N1**

Registration date: **2020-09-11, 1399/06/21**

Registration timing: **registered\_while\_recruiting**

Last update: **2020-09-11, 1399/06/21**

Update count: **0**

##### Registration date

2020-09-11, 1399/06/21

##### Registrant information

##### Name

Ali Ali Asgari

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 8490 2101

##### Email address

aliasgari@tums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-09-10, 1399/06/20

##### Expected recruitment end date

2020-12-20, 1399/09/30

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

A Multicentre, Quadruple-blind, Randomized, Parallel-group Study to Compare the Efficacy of Sofosbuvir and Daclatasvir vs. Placebo in the Outpatient Treatment of COVID-19 in adults

**Public title**

Efficacy of sofosbuvir and daclatasvir in ambulatory patients with coronavirus disease

**Purpose**

Treatment

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

Adult patients ( $\geq 18$  years) Onset of any one of the following symptoms within 7 days before presentation: fever, cough, chest discomfort, dyspnea, loss of taste or smell, severe body aches, weakness or fatigue  
Laboratory-confirmed SARS-CoV-2 infection by qualitative Reverse transcription polymerase chain reaction (RT-PCR) Able to provide written, informed consent Able to comply with study protocol for follow-up Not requiring hospitalization at the time of recruitment

**Exclusion criteria:**

Personal history of COVID-19 Pregnancy or breastfeeding  
Known severe chronic kidney disease requiring dialysis or eGFR  $< 30$  Taking medications that interfere with trial drugs including amiodarone or warfarin Heart rate  $< 50$  / min Receipt of any experimental treatment for SARS-CoV-2 (off-label, compassionate use, or trial related) within the 30 days prior to the time of the screening evaluation

**Age**

From **18 years** old

**Gender**

Both

**Phase**

3

**Groups that have been masked**

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

**Sample size**

Target sample size: **2000**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Participants will be randomly assigned to either SOF/DAC or control group with a 1:1 allocation using a central computer-generated randomisation schedule at DDRI in blocks of 4. The study drug and placebo will be packed in DDRI and labelled with a trial registration number

according to the randomization table. No information on the randomization schedule or any data on the contents of drug packs will be available to researchers or patients at recruitment sites.

**Blinding (investigator's opinion)**

Triple blinded

**Blinding description**

Enrolling physician, patient, researchers who assess outcomes and statistician will be blinded.

**Placebo**

Used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Digestive Diseases Research Institute- Tehran University of Medical Sciences

**Street address**

Shariati hospital, Jalal Al Ahmad

**City**

Tehran

**Province**

Tehran

**Postal code**

1411713135

**Approval date**

2020-08-15, 1399/05/25

**Ethics committee reference number**

IR.TUMS.DDRI.REC.1399.014

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

COVID-19

**ICD-10 code**

U07.1

**ICD-10 code description**

COVID-19 confirmed by laboratory testing

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

Difference between the two treatment arms in the proportion of participants classed as treatment failure at 14 days from enrolment. Treatment failure is defined as need for hospital admission or all-cause mortality within 14 days. Need for hospital admission is defined as the decision of a physician to admit the patient to a hospital

according to current national COVID-19 guidelines issued by the ministry of health. However, if the participant leaves the hospital against medical advice, it will still be considered a treatment failure.

**Timepoint**

14 days after enrolment

**Method of measurement**

Clinical follow-up

## Secondary outcomes

### 1

**Description**

Time to hospitalization (days from enrolment)

**Timepoint**

14 days after enrolment

**Method of measurement**

Clinical follow-up

### 2

**Description**

Duration of hospital stay (days)

**Timepoint**

One month after enrolment

**Method of measurement**

Clinical follow-up

### 3

**Description**

Need for ICU stay according to hospital records (yes/no)

**Timepoint**

One month after enrolment

**Method of measurement**

Clinical follow-up

### 4

**Description**

Need of mechanical ventilation according to hospital records (yes/no)

**Timepoint**

One month after enrolment

**Method of measurement**

Clinical follow-up

### 5

**Description**

Time to complete symptom resolution [patient becomes asymptomatic] from start of treatment (days from enrolment)

**Timepoint**

14 days after enrolment

**Method of measurement**

Clinical follow-up

### 6

**Description**

Hospital ER visit at the discretion of the patient (yes/no)

**Timepoint**

14 days after enrolment

**Method of measurement**

Clinical follow-up

### 7

**Description**

Adverse drug effects (yes/no)

**Timepoint**

14 days after enrolment

**Method of measurement**

Clinical follow-up

## Intervention groups

### 1

**Description**

Intervention group: A single daily tablet containing sofosbuvir 400mg and daclatasvir 60mg (Sovodak, Fanavaran Rojan Mohaghegh Daru Co., Tehran, Iran) for 10 days.

**Category**

Treatment - Drugs

### 2

**Description**

Control group: A single daily tablet containing placebo (similar to sovodak, Fanavaran Rojan Mohaghegh Daru Co., Tehran, Iran) for 10 days.

**Category**

Treatment - Drugs

## Recruitment centers

### 1

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

Tehran University of medical sciences

**Full name of responsible person**

Ali Ali Asgari

**Street address**

Shariati hospital, Jalal Al Ahmad

**City**

Tehran

**Province**

Tehran

**Postal code**

1411713135

**Phone**

+98 21 8241 5000

**Email**

aliasgari@tums.ac.ir

## Sponsors / Funding sources

### 1

**Sponsor**

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Shahin Merat

**Street address**

Shariati hospital, Jalal Al Ahmad

**City**

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**Postal code**

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**Phone**

+98 21 8241 5000

**Email**

shahin.merata@gmail.com

**Grant name**

ITPC-2020

**Grant code / Reference number**

ITPC-2020

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

No

**Title of funding source**

International Treatment Preparedness Coalition

**Proportion provided by this source**

100

**Public or private sector**

Public

**Domestic or foreign origin**

Foreign

**Category of foreign source of funding**

UN agencies and international organizations

**Country of origin****Type of organization providing the funding**

Academic

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

Tehran University of Medical Sciences

**Full name of responsible person**

Ali Ali Asgari

**Position**

Assistant professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Internal Medicine

**Street address**

Shariati hospital, Jalal Al Ahmad

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**Person responsible for updating data****Contact****Name of organization / entity**

Tehran University of Medical Sciences

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**Latest degree**

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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**

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