

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Sep 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 (≥ 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 (≥ 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

AgeFrom **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 sizeTarget 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

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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

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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

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

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Other areas of specialty/work

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

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Position

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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