Clinical Trial Protocol
Iranian Registry of Clinical Trials

02 Nov 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, Fanavaran 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
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

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Province
Tehran

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1411713135

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+98 21 8241 5000

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aliasgari@tums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
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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
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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
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