

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 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 ≥ 18 y; hospitalized patients with: Fever (Oral temperature ≥ 37.8 °C) and at least one of Respiratory rate >24 /min / O₂Sat $<94\%$ or the PaO₂/FiO₂ ratio <300 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 /min, taking Amiodarone, evidence of multiorgan failure, requiring mechanical ventilation at screening, eGFR < 50 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 (≤ 37.2 °C oral), respiratory rate (≤ 24 /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)

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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 ≥ 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 ≥ 37.8 °C) and at least one of Respiratory rate >24 /min / O₂Sat $<94\%$ or the PaO₂/FiO₂ ratio <300 mgHg ≤ 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 /min Taking Amiodarone Evidence of multiorgan failure Requiring mechanical ventilation at screening eGFR < 50 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

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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 (≤ 37.2 °C oral), respiratory rate (≤ 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

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Shariati Hospital, North Kargar Street, Tehran

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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

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3

Recruitment center**Name of recruitment center**

Baharloo hospital

Full name of responsible person

Hadiseh Hosemi Roudsari

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Baharloo Hospital - Behdari.street - Railway.square

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4

Recruitment center

Name of recruitment center
Sayad Shirazi Hospital
Full name of responsible person
Alireza Norouzi
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Digestive Disease Research Institute
Full name of responsible person
Dr Anahita Sadeghi
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Digestive Disease Research Institute, Shariati
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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

Fannavarán Rojan Mohaghegh Daru

Full name of responsible person

Fannavarán Rojan Mohaghegh Daru

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Number 10, block 8, Hamedan Street, North Kargar
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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

Fannavarán 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

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Assistant Professor

Latest degree

Subspecialist

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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

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

Tehran University of Medical Sciences

Full name of responsible person

Dr Anahita Sadeghi

Position**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