Clinical Trial Protocol
Iranian Registry of Clinical Trials

11 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 ≥ 18y; hospitalized patients with: Fever (Oral temperature ≥ 37.8 ℃) and at least one of Respiratory rate >24/min / O2Sat<94% or the Pa02/Fi02 ratio <300mgHg; 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 (≥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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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 ℃) and at least one of Respiratory rate >24/min / O2Sat<94% or the Pa02/Fi02 ratio <300mgHg ≤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
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 (≤37.2 °C oral), respiratory rate (≤24/minute on room air), and oxygen saturation (≥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

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Recruitment center

Name of recruitment center
Sina Hospital

Full name of responsible person
Mahnaz Montazeri

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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
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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
Fannavaran Rojan Mohaghegh Daru

Full name of responsible person
Fannavaran Rojan Mohaghegh Daru

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

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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
Fannavaran 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
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Person responsible for scientific inquiries

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Person responsible for updating data

Contact
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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
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