

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Sep 2026

Evaluation of efficacy and safety of Sovodak (Sofosbuvir+Daclatasvir) in combination with Ribavirin for mild to moderate hospitalized Covid-19 patients compared to standard care regimen (a randomized controlled trial)

Protocol summary

Study aim

To evaluate whether Sovodak (Sofosbuvir plus Daclatasvir) plus ribavirin increases significant clinical improvement as compared to standard of care in hospitalized patients with mild to moderate COVID-19

Design

This is a parallel 2-arm randomized, controlled, double-blind, single center study. 48 patients are enrolled and followed for 14 days and patients test for RT-PCR test from specimen of upper respiratory tract in start and end of study.

Settings and conduct

The study will be conducted in Razi hospital (Mazandaran) by investigators of pharmacy faculty, infectious disease and digestive disease research institute. clinical pharmacist who assess outcomes and the statistician analyzing the data will know the assigned treatment group. but the patients and physicians who treat patients will be blinded

Participants/Inclusion and exclusion criteria

All mild to moderate COVID-19 infected patients admitted to Razi hospital (Mazandaran), age 18-65 y; hospitalized patients with: Fever (Oral temperature ≥ 37.8 °C) and at least one of Respiratory rate $<24/\text{min}$ / $\text{O}_2\text{Sat} > 94\%$; PCR confirmed; diagnostic chest CT scan. Exclusion criteria: known allergic reaction to intervention drug, pregnant or breastfeeding, any prior experimental treatment for COVID-19, taking Amiodarone and Rifampin, evidence of multiorgan failure, requiring mechanical ventilation at screening, $\text{eGFR} < 50 \text{ mL/min}$

Intervention groups

48 eligible patients with mild to moderate COVID-19 in a 1:1 ratio: • in control group patients will be received Standard of care treatment and in intervention group patients will be received Sovodak tablet (Sofosbuvir 400mg/Daclatasvir 60mg) + Ribavirin

Main outcome variables

Clinical recovery (composite) within 14 days from initiation of study treatment did not need for ICU, invasive and non invasive mechanical ventilation, the time for eradication of virus from upper respiratory tract by RT-PCR test

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200328046886N1**

Registration date: **2020-04-12, 1399/01/24**

Registration timing: **retrospective**

Last update: **2020-04-12, 1399/01/24**

Update count: **0**

Registration date

2020-04-12, 1399/01/24

Registrant information

Name

Hamideh Abbaspour

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 11 4203 1035

Email address

dr.abbaspour1@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-03-05, 1398/12/15
Expected recruitment end date
 2020-03-20, 1399/01/01
Actual recruitment start date
 2020-03-20, 1399/01/01
Actual recruitment end date
 2020-04-08, 1399/01/20
Trial completion date
 2020-05-04, 1399/02/15

Scientific title
 Evaluation of efficacy and safety of Sovodak (Sofosbuvir+Daclatasvir) in combination with Ribavirin for mild to moderate hospitalized Covid-19 patients compared to standard care regimen (a randomized controlled trial)

Public title
 The effectiveness of Sovodak (sofosbuvir+daclatasvir) in Covid-19 patients

Purpose
 Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 patients with signing Informed Consent Form Willing Age 18-65 years old Laboratory (RT-PCR) confirmed infection with 2019-nCoV or 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% ≤ 8 days since illness onset
Exclusion criteria:
 Known allergic reaction to Sofosbuvir or Daclatasvir Pregnant or breastfeeding women Taking Amiodarone Evidence of multiorgan failure Requiring mechanical ventilation at screening eGFR < 50 mL/min Taking enzyme inducer like Rifampin Receipt of any experimental treatment for COVID-19 prior to the time of the screening Patient with Hb < 9

Age
 From 18 years old to 65 years old

Gender
 Both

Phase
 3

Groups that have been masked

- Participant
- Care provider

Sample size
 Target sample size: 48
 Actual sample size reached: 48

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)
 Double blinded

Blinding description
 clinical pharmacist who assess outcomes and the statistician analyzing the data will not be blinded. Physicians who treat patients and the patients will be blinded

Placebo
 Not used

Assignment
 Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Mazandaran University Of Medical Science

Street address

Faculty of pharmacy, Payambar Azam academic complex, 18 km of Khazar Abad Ave, Sari

City

Sari

Province

Mazandaran

Postal code

4763947444

Approval date

2020-04-02, 1399/01/14

Ethics committee reference number

IR.MAZUMS.REC.1399.019

Health conditions studied

1

Description of health condition studied

The effectiveness of Sovodak in patients with novel Corona Virus

ICD-10 code

U07.1 COVI

ICD-10 code description

ICD-10 code of 'U07.1 COVID-19, virus identified' is assigned to a disease diagnosis of COVID-19 confirmed by laboratory testing.

Primary outcomes

1

Description

Need of invasive and non invasive mechanical ventilation ,need of oxygen supplement , the median time for recovery and well-being

Timepoint

daily in all duration of study

Method of measurement

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: sovodak+ribavirin

Category

Treatment - Drugs

2

Description

Control group: standard care regimen

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Razi Hospital

Full name of responsible person

Hamideh Abbaspour Kasgari

Street address

Razi educational center, Yousefreza Ave,
Qhaemshahr, Mazandaran

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dr.abbaspour1@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Majid Saeedi

Street address

Mazandaran University of Medical Sciences, Valie-Asr
Boulevard, Sari, Mazandaran, Iran

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DR.ABBASPOUR1@YAHOO.COM

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Mazandaran University of Medical Sciences

Proportion provided by this source

100

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

Person responsible for general inquiries

Contact

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Hamideh Abbaspour Kasgari

Position

Associate Professor

Latest degree

Specialist

Other areas of specialty/work

clinical pharmacist

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Faculty of pharmacy, Payambar Azam academic
complex, 18 km of Khazar Abad Ave, Sari

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Mazandaran University of Medical Sciences

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associate professor

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Person responsible for updating data

Contact

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is 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

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

all collected deidentified IPD

When the data will become available and for how long

starting 1 month after publication

To whom data/document is available

people working in academic institutions

Under which criteria data/document could be used

in situation that investigator willing

From where data/document is obtainable

email addresses

What processes are involved for a request to access data/document

in short time after request with email will be available

Comments