

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 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),age18-65 y; hospitalized patients with: Fever (Oral temperature  $\geq 37.8$  °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  $\geq 37.8$  °C) and at least one of Respiratory rate  $< 24/\text{min}$  /  $\text{O}_2\text{Sat} > 94\%$   $\leq 8$  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  $\text{eGFR} < 50$  mL/min Taking enzyme inducer like Rifampin Receipt of any experimental treatment for COVID-19 prior to the time of the screening Patient with  $\text{Hb} < 9$

#### 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

By designed investigator checklist

## 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

#### City

Qhaemshahr

#### Province

Mazandaran

#### Postal code

#### Phone

+98 11 4221 8018

#### Fax

#### Email

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

#### City

Sari

#### Province

Mazandaran

#### Postal code

4815733971

#### Phone

+98 11 4203 1035

#### Email

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

#### Street address

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

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#### Province

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## Person responsible for scientific 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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**Email**

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**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Mazandaran University of Medical Sciences

**Full name of responsible person**

Hamideh Abbaspour Kasgari

**Position**

Associate professor

**Latest degree**

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**Other areas of specialty/work**

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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**