Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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 speciem 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 ≥ 37.8 ℃) and at least one of Respiratory rate <24/min / O2Sat>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, eGFR< 50 mL/min

Intervention groups

48 eligible patients with mild to moderate COVID-19 in a 1:1 ratio: • in control group patients will be recieved Standard of care treatment and in intervention group patients will be recieved 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 ℃) 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

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
City
Sari
Province
Mazandaran
Postal code
4763947444
Phone
+98 11 4203 1035
Email
dr.abbaspour1@yahoo.com

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

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

City
Sari

Province
Mazandaran

Postal code
4763947444

Phone
+98 11 4203 1035

Email
dr.abbaspour1@yahoo.com

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
Specialist

Other areas of specialty/work
clinical pharmacy

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

City
Sari

Province
Mazandaran

Postal code
4763947444

Phone
+98 11 4203 1035

Email
dr.abbaspour1@yahoo.com

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 invastigator 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