Clinical Trial Protocol
Iranian Registry of Clinical Trials
14 Dec 2020

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), age 18-65 y; hospitalized patients with: Fever (Oral temperature ≥ 37.8 °C) 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
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Hamideh Abbaspour
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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

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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
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Razi educational center, Yousefreza Ave, Qhaemshahr, Mazandaran
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Sponsors / Funding sources

1
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Name of organization / entity
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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