

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

04 Oct 2023

### Comparison of the effect of Sofosbuvir + Daclatasvir (Sovodac) and Ribavirin in Covid-19 Patients with Severe Symptoms

#### Protocol summary

##### Study aim

Comparison of the effect of two drugs Daclatasvir + Sofosbuvir and Ribavirin in COVID-19 patients with severe symptoms

##### Design

The study is a open label , non-randomized and parallel clinical trial. The study population includes all patients with COVID-19 referring to Abadan hospitals. All patients who refer to Abadan hospitals in a period of time and their testing is positive, which includes 62 people, who will be in two groups: Doclatasavir + Sophosbovir and Ribavirin.

##### Settings and conduct

the drug used in this study in both groups is similar in appearance.was performed on 62 patients with severe symptoms of COVID-19 who were admitted to the infectious ward of Ayatollah Taleghani Hospital in Abadan and if they were hospitalized. The study was approved by the Ethics Committee of Abadan University of Medical Sciences. All patients eligible for inclusion in this study were adequately informed about the procedure and side effects of the drugs used, assured of the confidentiality of their information, and then a written consent was obtained. Patients also had the right to withdraw from the research team at any time.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: positive COVID-19 with severe symptoms and positive RT-PCR assay of nasopharyngeal samples Exclusion criteria: patients under 18 years, pregnant and breast feeding women

##### Intervention groups

The first group: Daclatasvir + Sofosbuvir The second group: Ribavirin

##### Main outcome variables

level of consciousness, Respiratory rate, blood pressure and arterial oxygen saturation and changes in laboratory factors, gastrointestinal disorder, number of days of hospitalization and mortality rate.

#### General information

##### Reason for update

Explain the release schedule as well as update the primary and secondary variables

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20200324046850N2**

Registration date: **2020-03-29, 1399/01/10**

Registration timing: **registered\_while\_recruiting**

Last update: **2020-05-01, 1399/02/12**

Update count: **4**

##### Registration date

2020-03-29, 1399/01/10

##### Registrant information

##### Name

Sara Mobarak

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 61 5326 7800

##### Email address

s.mobarak@abadanums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-03-18, 1398/12/28

##### Expected recruitment end date

2020-04-16, 1399/01/28

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

## Scientific title

Comparison of the effect of Sofosbuvir + Daclatasvir (Sovodac) and Ribavirin in Covid-19 Patients with Severe Symptoms

## Public title

Comparison of the effect of Sofosbuvir + Daclatasvir (Sovodac) and Ribavirin in Covid-19

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

COVID-19 patients that have positive PCR test of nasopharyngeal sample or have bilateral multi-lobar ground glass opacity in CT scan O2 saturation under 94% or respiratory rate above 24 or decreased level of consciousness

### Exclusion criteria:

patients under 18 years pregnant or breast feeding women patients did not consent to participate in the study patients who took any complementary medicine safety problem for patients patients with any allergy or hypersensitivity to Sofosbuvir + Daclatasvir or Ribavirin or with major interaction with other medicine

## Age

From **18 years** old

## Gender

Both

## Phase

2

## Groups that have been masked

*No information*

## Sample size

Target sample size: **62**

## Randomization (investigator's opinion)

Not randomized

## Randomization description

## Blinding (investigator's opinion)

Not blinded

## Blinding description

## Placebo

Not used

## Assignment

Parallel

## Other design features

-

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Abadan school of medical sciences

##### Street address

-Abadan School of Medical Sciences, Deputy of Education in front of Ayatollah Jamie Airport

##### City

Abadan

##### Province

Khouzestan

##### Postal code

6313833177

##### Approval date

2020-03-18, 1398/12/28

##### Ethics committee reference number

IR.ABADANUMS.REC.1398.113

## Health conditions studied

### 1

#### Description of health condition studied

COVID-19

#### ICD-10 code

U07.1

#### ICD-10 code description

2019-nCOV disease

## Primary outcomes

### 1

#### Description

Time to clinical improvement defined as start of taking medication time to alive hospital discharge

#### Timepoint

The beginning of the study , the time of discharge and 21 days after discharge

#### Method of measurement

Medical record

## Secondary outcomes

### 1

#### Description

Duration of hospitalization

#### Timepoint

Time of discharge

#### Method of measurement

Number of hospital days

### 2

#### Description

Duration of stay at ICU

#### Timepoint

Daily

#### Method of measurement

Number of days of hospitalization in ICU

### 3

#### Description

Mortality rate

#### Timepoint

Daily

#### Method of measurement

Medical record

#### 4

**Description**

Respiratory rate

**Timepoint**

Daily

**Method of measurement**

Count the number of breaths per minute

#### 5

**Description**

laboratory variables

**Timepoint**

The beginning of the study and the time of discharge

**Method of measurement**

Medical record

#### 6

**Description**

Adverse events

**Timepoint**

Time of discharge

**Method of measurement**

Medical record

### Intervention groups

#### 1

**Description**

lopinavir (50 mg) -ritonavir (200 mg) 2 tablets every 12 hours until the patient's clinical symptoms improve + hydroxychloroquine (200 mg) two tablets one dose + sofosbuvir (400 mg)- daclatasvir (60 mg) take one tablet daily until clinical symptoms improve

**Category**

Treatment - Drugs

#### 2

**Description**

Intervention group 2: lopinavir (50 mg) -ritonavir (200 mg) 2 tablets every 12 hours until the patient's clinical symptoms improve + hydroxychloroquine (200 mg) two tablets one dose + ribavirin (200 mg) 6 tablets every 12 hours until clinical symptoms improve

**Category**

Treatment - Drugs

### Recruitment centers

#### 1

**Recruitment center****Name of recruitment center**

Ayatollah Taleghani Hospital in Abadan

**Full name of responsible person**

Sara Mobarak

**Street address**

-Abadan School of Medical Sciences, Deputy of Education in front of Ayatollah Jamie Airport

**City**

Abadan

**Province**

Khuzestan

**Postal code**

6313833177

**Phone**

+98 61 5326 7800

**Email**

s.mobarak@abadanums.ac.ir

### Sponsors / Funding sources

#### 1

**Sponsor****Name of organization / entity**

Abadan University of Medical Sciences

**Full name of responsible person**

Sara Mobarak

**Street address**

-Abadan School of Medical Sciences, Deputy of Education in front of Ayatollah Jamie Airport

**City**

Abadan

**Province**

Khuzestan

**Postal code**

6313833177

**Phone**

+98 61 5326 7800

**Email**

s.mobarak@abadanums.ac.ir

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Abadan 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**

Abadan University of Medical Sciences

**Full name of responsible person**

Sara Mobark

**Position**

Associate Professor

**Latest degree**

Specialist  
**Other areas of specialty/work**  
infections diseases  
**Street address**  
Deputy of Education in front of Ayatollah Jamie Airport  
**City**  
Abadan  
**Province**  
Khouzestan  
**Postal code**  
6313833177  
**Phone**  
+98 61 5326 7800  
**Email**  
s.mobarak@abadanums.ac.ir

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
Abadan University of Medical Sciences  
**Full name of responsible person**  
Sara Mobarak  
**Position**  
Associate professor  
**Latest degree**  
Specialist  
**Other areas of specialty/work**  
Infections diseases  
**Street address**  
- Deputy of Education in front of Ayatollah Jamie Airport  
**City**  
Abadan  
**Province**  
Khouzestan  
**Postal code**  
6313833177  
**Phone**  
+98 61 5326 7800  
**Fax**  
**Email**  
S.mobarak@abadanums.ac.ir

## Person responsible for updating data

### Contact

**Name of organization / entity**  
Abadan University of Medical Sciences  
**Full name of responsible person**  
Sara Mobarak  
**Position**  
Associate professor  
**Latest degree**

Specialist  
**Other areas of specialty/work**  
Infections diseases  
**Street address**  
-Abadan School of Medical Sciences, Deputy of Education in front of Ayatollah Jamie Airport  
**City**  
Abadan  
**Province**  
Khouzestan  
**Postal code**  
6313833177  
**Phone**  
+98 61 5326 7800  
**Fax**  
**Email**  
S.mobarak@abadanums.ac.ir

## 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 data can be shared after the participants in the study are unrecognizable.

### When the data will become available and for how long

The data access period after printing the article

### To whom data/document is available

-The data in this study will be available to researchers working at academic and scientific institutions, as well as the Food and Drug Administration.

### Under which criteria data/document could be used

- Any analysis can be done with the consent of the main researcher.

### From where data/document is obtainable

-s.mobarak@abadanums.ac.ir

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

-The researcher or pharmaceutical company can send their request to the academic email after sending the documents to confirm their original identity.

### Comments

-