

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Jun 2026

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

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

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Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

Abadan University of Medical Sciences

Full name of responsible person

Sara Mobarak

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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
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Person responsible for scientific inquiries

Contact

Name of organization / entity
Abadan University of Medical Sciences
Full name of responsible person
Sara Mobarak
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Person responsible for updating data

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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 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

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