Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Oct 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
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
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
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Province
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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

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Sara Mobarak

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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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