# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

02 Nov 2026

## Efficacy of Daclatasvir+Sofosbuvir in patients with severe acute respiratory syndrome coronavirus (SARS-COVID-19)

### Protocol summary


**Study aim**
Determination of the efficacy of daclatasvir + sofosbuvir in patients with COVID-19

**Design**
Using a table of random numbers, they are divided into intervention and control groups. The volume of each group is 35 patients. The present study is a double-blind study.

**Settings and conduct**
Patients admitted to Razi Hospital in Ahvaz will be divided into two groups based on a table of random numbers. Radiologists, treatment outcome evaluators, and statisticians will be unaware of assignments to groups, but patients and physicians will be aware of treatment groups.

**Participants/Inclusion and exclusion criteria**
Admission of hospitalized patients over 18 years of age; withdrawal of allergic reaction; pregnancy or lactation; any previous intervention; use of Amiodarone; need for mechanical ventilation and EGFR less than 50.

**Intervention groups**
In the intervention group, patients did not receive one Daclatasvir / Sofosbuvir tablet daily for 7 days in addition to the national recommendations, and the control group did not receive the drug.

**Main outcome variables**
The primary outcome is clinical improvement within 14 days of starting treatment, for which fever, respiration rate per minute, and oxygen saturation are determined daily. Criteria for clinical improvement include fever normalization (37.2 ° C), respiration rate (≤ 24 per minute), and oxygen saturation (94% in room air) and are stable for up to 24 hours.


### General information

**Reason for update**
**Acronym**
**IRCT registration information**


IRCT registration number: **IRCT20200816048422N1**
Registration date: **2020-10-16, 1399/07/25**
Registration timing: **retrospective**

Last update: **2020-10-16, 1399/07/25**
Update count: **0**


**Registration date**
2020-10-16, 1399/07/25


**Registrant information**
**Name**
Zahra Fakhrae
**Name of organization / entity**
**Country**
Iran (Islamic Republic of)
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**Recruitment status**
**Recruitment complete**
**Funding source**

**Expected recruitment start date**
2020-06-25, 1399/04/05
**Expected recruitment end date**
2020-08-21, 1399/05/31
**Actual recruitment start date**
empty
**Actual recruitment end date**
empty
**Trial completion date**
empty

**Scientific title**
Efficacy of Daclatasvir+Sofosbuvir in patients with severe acute respiratory syndrome coronavirus (SARS-COVID-19)

**Public title**

Efficacy of Daclatasvir+Sofosbuvir in patients with severe acute respiratory syndrome coronavirus (SARS-COVID-19)

**Purpose**
Treatment

**Inclusion/Exclusion criteria**

**Inclusion criteria:**
Age over 18 years old Respiratory rate more than 30 per minute Oxygen saturation less than 93% Confirmation of pneumonia by diagnostic CT scan of the chest

**Exclusion criteria:**
Taking the drug Amiodarone Kidney failure

**Age**
From **18 years** old

**Gender**
Both

**Phase**
1-2

**Groups that have been masked**

- Participant
- Care provider

**Sample size**
Target sample size: **70**

**Randomization (investigator's opinion)**
Randomized

**Randomization description**
According to the patients' block classification table, eleven blocks of six are divided into two groups a and b and the intervention is considered by the researcher of group a and the control group b. According to the date of hospitalization, patients were divided into groups a and b, respectively, according to blockade. The concealment of the study is double-blind.

**Blinding (investigator's opinion)**
Double blinded

**Blinding description**
After providing explanations to patients by the researcher using a random drug process, the drug is prescribed in such a way that the researcher and the patient do not know about the drug and only the treating physician knows about the drug.

**Placebo**
Not used

**Assignment**
Single

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**

**Name of ethics committee**
Ethics committee of jundishapoor ahwaz University of Medical Sciences

**Street address**
amaniye st razi hospital

**City**
ahwaz

**Province**
Khouzestan

**Postal code**
1494161965

**Approval date**
2020-06-20, 1399/03/31

**Ethics committee reference number**
IR.AJUMS.REC.1399.300

## Health conditions studied

### 1

**Description of health condition studied**
COVID-19

**ICD-10 code**
U07.1

**ICD-10 code description**
COVID -19, virus identified

## Primary outcomes

### 1

**Description**
Respiratory rate

**Timepoint**
14th day

**Method of measurement**
physical exam

### 2

**Description**
Arterial oxygen

**Timepoint**
7th day

**Method of measurement**
Physical examination

### 3

**Description**
Requires mechanical ventilation

**Timepoint**
7th day

**Method of measurement**
Physical examination

### 4

**Description**
Death

**Timepoint**
7th day

**Method of measurement**
Physical examination

**5**

**Description**
Chest changes
**Timepoint**
7th day
**Method of measurement**
Physical examination

## Secondary outcomes

**1**

**Description**
Secondary consequences include the need for mechanical ventilation, chest changes (day 14 or earlier as determined by the physician), serious accidents, and mortality.
**Timepoint**
14th day
**Method of measurement**
Physical examination

## Intervention groups

**1**

**Description**
Patients in the intervention group receive one Daclatasvir / Sofosbuvir 60/400 mg tablet (Danesh Pharmaceutical Development Company) daily for 7 days.
**Category**
Treatment - Drugs

**2**

**Description**
Control group: Received national protocol drugs.
**Category**
Treatment - Drugs

## Recruitment centers

**1**

**Recruitment center**
**Name of recruitment center**
Razi hospital
**Full name of responsible person**
Dr Fatemeh Ahmadi
**Street address**
Razi hospital, Palestine Street
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**Postal code**
1965149416
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## Sponsors / Funding sources

**1**

**Sponsor**
**Name of organization / entity**
Ahvaz University of Medical Sciences
**Full name of responsible person**
Dr. Mohammad Badawi
**Street address**
Jundishapur University of Medical Sciences, Golestan Town
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**Email**
info@ajums.ac.ir
**Web page address**
**Grant name**
**Grant code / Reference number**
**Is the source of funding the same sponsor organization/entity?**
No
**Title of funding source**
Ahwaz Jundishapur 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**
Ahvaz University of Medical Sciences
**Full name of responsible person**
Dr. Zahrz Fakhrae
**Position**
resident
**Latest degree**
Medical doctor
**Other areas of specialty/work**
Infectious diseases
**Street address**
Opposite number 61965 14941, in front of the Governorate, Palestine Street
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## Person responsible for scientific inquiries

**Contact**
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## Person responsible for updating data

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**
Undecided - It is not yet known if there will be a plan to make this available
**Study Protocol**
Undecided - It is not yet known if there will be a plan to make this available
**Statistical Analysis Plan**
Undecided - It is not yet known if there will be a plan to make this available
**Informed Consent Form**
No - There is not a plan to make this available
**Clinical Study Report**
Undecided - It is not yet known if there will be a plan to make this available
**Analytic Code**
Undecided - It is not yet known if there will be a plan to make this available
**Data Dictionary**
Undecided - It is not yet known if there will be a plan to make this available