

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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 ( $\leq 24$  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)

###### Phone

+98 61 3333 5937

###### Email address

z.fakhrae@yahoo.com

##### 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 Jundishapur Ahwaz University of Medical Sciences

##### Street address

amaniye st razi hospital

#### City

ahwaz

#### Province

Khuzestan

#### 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

#### **City**

Ahwaz

#### **Province**

Khuzestan

#### **Postal code**

1965149416

#### **Phone**

+98 61 3333 5935

#### **Email**

z.fakhræ@yahoo.com

## **Sponsors / Funding sources**

### 1

### **Sponsor**

#### **Name of organization / entity**

Ahwaz University of Medical Sciences

#### **Full name of responsible person**

Dr. Mohammad Badawi

#### **Street address**

Jundishapur University of Medical Sciences, Golestan Town

#### **City**

Ahwaz

#### **Province**

Khuzestan

#### **Postal code**

15794 - 61357

#### **Phone**

+98 61 3333 3311

#### **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**

Ahwaz University of Medical Sciences

#### **Full name of responsible person**

Dr. Zahrz Fakhræ

#### **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

#### **City**

Ahwaz

#### **Province**

Khuzestan

**Postal code**  
61965 14941  
**Phone**  
+98 61 3333 5935  
**Email**  
z.fakhræ@yahoo.com

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
Ahvaz University of Medical Sciences  
**Full name of responsible person**  
Dr. Fatemeh Ahmadi  
**Position**  
Assistant Professor  
**Latest degree**  
Specialist  
**Other areas of specialty/work**  
Infectious diseases  
**Street address**  
Opposite number 61965 14941, in front of the Governorate, Palestine Street  
**City**  
Ahwaz  
**Province**  
Khouzestan  
**Postal code**  
61965 14941  
**Phone**  
+98 61 3333 5935  
**Email**  
ahmadi-f@ajums.ac.ir

## Person responsible for updating data

### Contact

**Name of organization / entity**  
Ahvaz University of Medical Sciences  
**Full name of responsible person**

Dr. Zahra Fakhraei  
**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  
**City**  
Ahwaz  
**Province**  
Khouzestan  
**Postal code**  
6196514941  
**Phone**  
+98 61 3333 5935  
**Email**  
z.fakhræ@yahoo.com

## 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