

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 (≤ 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

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Khuzestan

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1965149416

Phone

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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

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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

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

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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
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Person responsible for updating data

Contact

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

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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