

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jun 2026

Effect of edaravone on clinical improvement and outcome of patients with respiratory distress syndrome caused by COVID-19

Protocol summary

Study aim

The effect of Edaravone on the course of clinical signs in patients with COVID-19 will be evaluated.

Design

A clinical trial with a control group, with parallel groups, simple-randomly assigned to intervention and control groups, Phase 3, 38 patients

Settings and conduct

This study will be performed in Imam Reza Hospital, Tabriz, Iran. 38 patients will be divided into two groups (15 in each group) by simple randomization. Patients in the control group will be prescribed a standard regimen. Patients in the intervention group, in addition to the treatment approved by the Ministry of Health, will receive 30 mg Edaravone by intravenous infusion for 3 day. Lungs' CT scan, hospitalization period, need to intubation, and mortality rate will be assessed.

Participants/Inclusion and exclusion criteria

Patients with COVID-19 with mild to moderate pneumonia; 18 years to 80 Years; both genders. Exclusion criteria: Pregnant or lactating women; patients with an active thrombotic event; severe respiratory failure.

Intervention groups

will receive a standard regimen for COVID-19 plus Edaravone. Control group: will receive a standard regimen for COVID-19.

Main outcome variables

Symptoms of the disease; mortality rate; hospitalization period

General information

Reason for update

According to the conducted changes during the project, editions were made to the inclusion and exclusion criteria, the method of blinding, the number of achieved patients and the drug dose.

Acronym

IRCT registration information

IRCT registration number: **IRCT20200317046797N6**

Registration date: **2020-06-18, 1399/03/29**

Registration timing: **prospective**

Last update: **2022-03-09, 1400/12/18**

Update count: **1**

Registration date

2020-06-18, 1399/03/29

Registrant information

Name

Sepideh Zununi Vahed

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 41 3336 9331

Email address

sepide.zununi@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-06-21, 1399/04/01

Expected recruitment end date

2020-07-22, 1399/05/01

Actual recruitment start date

2020-12-21, 1399/10/01

Actual recruitment end date

2021-08-30, 1400/06/08

Trial completion date

empty

Scientific title

Effect of edaravone on clinical improvement and outcome of patients with respiratory distress syndrome caused by COVID-19

Public title

Edaravone in COVID-19

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients with COVID-19-induced pneumonia confirmed with Polymerase chain reaction (PCR) Patients with COVID-19-induced pneumonia confirmed with chest CT scan results 18 to 80 years old Patients with acute respiratory distress syndrome (ARDS) according to Berlin ARDS criteria

Exclusion criteria:

Patients who are participating in other drug clinical trials Pregnant or lactating women Patient with drug allergy Patients on mechanical ventilation Patients with expected survival duration < 24 h

Age

From **18 years** old to **80 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **30**

Actual sample size reached: **38**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization will be generated with a computer from 1 to 38. The computer will divide the digits between the two groups (edaravone and control). According to the sequences of admission, they will go to the control or the intervention group regarding the computerized random list.

Blinding (investigator's opinion)

Double blinded

Blinding description

The packaging of the drugs in this study will be similar to the other drugs related to COVID-19 therapy and the researcher will not be aware from the grouping of patients. Therefore, patients and researchers will be blinded.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Tabriz University of Medical Sciences

Street address

Tabriz University of Medical Sciences, Golgasht Street

City

Tabriz

Province

East Azarbaijan

Postal code

5166614766

Approval date

2020-05-18, 1399/02/29

Ethics committee reference number

IR.TBZMED.REC.1399.128

Health conditions studied**1****Description of health condition studied**

Patients with COVID-2019

ICD-10 code

B34.2

ICD-10 code description

Coronavirus infection, unspecified

Primary outcomes**1****Description**

Hospitalization days

Timepoint

At baseline and discharge time

Method of measurement

Counting the days

2**Description**

Need for mechanical ventilation

Timepoint

From baseline to discharge time

Method of measurement

Observation and documents

3**Description**

Condition of discharge (death or recovery)

Timepoint

End of hospitalization

Method of measurement

Observation and documents

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: 15 patients with COVID-19 in addition to a standard regimen will receive 30 mg intravenous infusion edaravone (C₁₀H₁₀N₂O, Zist Daroo Co., Iran) every 12 hours for 1 day from the beginning of hospitalization

Category

Treatment - Drugs

2

Description

Control group: 15 patients will receive only standard regimen of COVID-2019

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imamreza Hospita of Tabriz

Full name of responsible person

Mojtaba Varshochi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

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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

Tabriz 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

Tabriz University of Medical Sciences

Full name of responsible person

Mojtaba Varshochi

Position

Professor

Latest degree

Specialist

Other areas of specialty/work

Infectious diseases

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Position

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Full name of responsible person

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Other areas of specialty/work

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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

Undecided - It is not yet known if there will be 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