

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

30 May 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 (C<sub>10</sub>H<sub>10</sub>N<sub>2</sub>O, 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

##### Street address

Imamreza Hospital, Golgasht Street

##### City

Tabriz

##### Province

East Azarbaijan

##### Postal code

5166614756

##### Phone

+98 41 3334 7054

##### Email

imamreza@tbzmed.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Tabriz University of Medical Sciences

##### Full name of responsible person

Dr Mohammad Samiei

##### Street address

3th floor of Tabriz University of Medical Sciences  
Central Building, Golgasht Street, Tabriz

##### City

Tabriz

##### Province

East Azarbaijan

##### Postal code

5166614766

##### Phone

+98 41 3335 7310

##### Email

Samiei.moh@gmail.com

##### 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

##### Street address

Daneshgah Street, Tabriz University of Medical Sciences

##### City

Tabriz

##### Province

East Azarbaijan

##### Postal code

5166614756

##### Phone

+98 41 3335 2898

##### Email

varshochim@tbzmed.ac.ir

## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Tabriz University of Medical Sciences

##### Full name of responsible person

Mohammadreza Ardalan

##### Position

Professor

##### Latest degree

Subspecialist

##### Other areas of specialty/work

Internal Medicine

**Street address**

Tabriz University of Medical Sciences

**City**

Tabriz

**Province**

East Azarbaijan

**Postal code**

5166614766

**Phone**

+98 41 3336 9331

**Email**

ardalan34@yahoo.com

**Province**

East Azarbaijan

**Postal code**

5166614766

**Phone**

+98 41 3336 9331

**Email**

sepide.zununi@gmail.com

**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Tabriz University of Medical Sciences

**Full name of responsible person**

Sepideh Zununi Vahed

**Position**

Assistant Prof.

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Medical Biotechnology

**Street address**

Tabriz University of Medical Sciences

**City**

Tabriz

**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