

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

20 Oct 2020

### 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, 30 patients

##### Settings and conduct

This study will be performed in Imam Reza Hospital, Tabriz, Iran. 30 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 intravenous infusion every 12 hours for 1 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

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20200317046797N6**

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

Registration timing: **prospective**

Last update: **2020-06-18, 1399/03/29**

Update count: **0**

##### 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

empty

##### Actual recruitment end date

empty

##### 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

Health service research

##### Inclusion/Exclusion criteria

**Inclusion criteria:**

Patients with COVID-19-induced pneumonia confirmed with Polymerase chain reaction (PCR) Both genders 18 to 80 years old Patients or authorized family members volunteered to participate in this study and signed informed consent.

**Exclusion criteria:**

Patients who are participating in other drug clinical trials  
Pregnant or lactating women Patient with active thrombotic event Patients with severe respiratory failure

**Age**

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

**Gender**

Both

**Phase**

3

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **30**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Simple randomization will be generated with a computer from 1 to 30. 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)**

Not blinded

**Blinding description**

**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

### 4

**Description**

Period of mechanical ventilation

**Timepoint**

End of hospitalization

**Method of measurement**

Documents of hospitalization

## 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

**Street address**

Imamreza Hospital, Golgasht Street

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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

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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

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**Person responsible for scientific inquiries**

**Contact**

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**Full name of responsible person**

Mohammadreza Ardalan

**Position**

Professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Internal Medicine

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**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

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**Postal code**

5166614766

**Phone****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