Clinical Trial Protocol
Iranian Registry of Clinical Trials

13 Nov 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
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Iran (Islamic Republic of)
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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
Immamreza Hospita of Tabriz
Full name of responsible person
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
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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