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

Immamreza 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

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
Province
East Azarbaijan
Postal code
5166614766
Phone
+98 41 3336 9331
Email
sepide.zununi@gmail.com

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