Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Effectiveness of Borage based solutions in cytokine's levels in covid-19 ARDS patients with elevated Extravascular Lung Water(EVLW)

Protocol summary

Study aim
Reducing in mortality and improve oxygenation in covid-19 patient's
Design
covid-19patients admitted to the intensive care unit and who had severe respiratory failure and lack of adequate response to treatment were included in the group, and give 5cc Borage suspension orally for 7 days. The general symptoms of patients and CT scans of patients were noted.
Settings and conduct
Patients admitted to the ICU who have respiratory failure and have not responded to treatment. They are selected and give Borage suspension orally and patients' symptoms are noted
Participants/Inclusion and exclusion criteria
patient's admited in ICU and wards
Intervention groups
covid-19patients admitted to the intensive care unit and who had severe respiratory failure
Main outcome variables
improve oxygenation improve ct scans

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20150107020592N28**
Registration date: **2020-06-18, 1399/03/29**
Registration timing: **registered_while_recruiting**

Last update: **2020-06-18, 1399/03/29**
Update count: **0**
Registration date
2020-06-18, 1399/03/29

Registrant information

Name
Seyed Mohammad Reza Hashemian
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 21 2610 9944
Email address
iran.criticalcare@yahoo.com

Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2020-03-20, 1399/01/01
Expected recruitment end date
2020-06-21, 1399/04/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Effectiveness of Borage based solutions in cytokine's levels in covid-19 ARDS patients with elevated Extravascular Lung Water(EVLW)

Public title
Effectiveness of borage based solutions in cytokine's levels in covid-19 ARDS patients
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Covid-19 patients Non-Intubated payients Age between 18-80
Exclusion criteria:
Allergy to Borage Intubated patients
Age

From **18 years** old

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **50**

Randomization (investigator's opinion)
Not randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Masih Daneshvari Hospital the Edjucational , Research and Treatment center.

Street address
Masih Daneshvari Hospital, Darabad Avenue, Shahid Bahonar roundabout, Tehran, Iran

City
Tehran

Province
Tehran

Postal code
1956944413

Approval date
2020-04-07, 1399/01/19

Ethics committee reference number
IR.SBMU.NRITLD.REC.1399.059

Health conditions studied

1

Description of health condition studied
covid-19

ICD-10 code
U07.1

ICD-10 code description
covid19 disease

Primary outcomes

1

Description
Improve oxygenation

Timepoint
0,1,2,3,7 after treatment with Borage

Method of measurement
Pulse oximeter

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: patient under Borage treatment: Patients who have acute respiratory failure due to covid-19 and do not respond to antiretroviral therapy due to the unknown nature of the disease to reduce inflammatory cytokines in patients give Borage suspension orally and seven days continue and the general condition of patients and symptoms Patient and CT-scans are checked

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Masih Daneshvari Hospital

Full name of responsible person
Seyyed Mohammadreza Hashemian

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Masih Daneshvari Hospital, Darabad, Niavaran Sq, Tehran, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Afshin Zarghi

Street address

7th Floor, Bldg No.2 , Arabi Ave, Daneshjoo Blvd, Velenjak

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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
Shahid Beheshti 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
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Seyed Mohammad Reza Hashemian

Position
Associate Professor

Latest degree
Subspecialist

Other areas of specialty/work
Anesthesiology

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Person responsible for scientific inquiries

Contact

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Position
Associate Professor

Latest degree
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Person responsible for updating data

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Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All patient information can be published after deleting the name

When the data will become available and for how long

It will take a month from the time of application

To whom data/document is available

All professors of medical universities in the country

Under which criteria data/document could be used

If the professors present their proposal and letter from their university by sending a message to Dr. Hashemian's e-mail, they will send their e-mail request and the names and numbers of the patients will be deleted and their questionnaires, data and analysis will be sent to their e-mails.

From where data/document is obtainable

professor hashemian in masih daneshvari hospital

What processes are involved for a request to access data/document

one month

Comments