

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 May 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-19 patients 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 admitted in ICU and wards

Intervention groups

covid-19 patients 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 patients 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 Educational ,
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

Street address
Masih Daneshvari Hospital, Darabad, Niavaran Sq,
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iran.criticalcare@yahoo.com

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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Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Seyed Mohammad Reza Hashemian

Position

Associate Professor

Latest degree

Subspecialist

Other areas of specialty/work

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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