

# 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,  
Tehran, Iran

**City**

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**Province**

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**Phone**

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**Email**

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

**City**

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**Province**

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**Phone**

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**Email**

iran.criticalcare@yahoo.com

**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

**Street address**

Masih Daneshvari Hospital, Darabad, Niavaran Street,  
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198396-3113

**Phone**

+98 912 111 9279

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smrhashemian@sbmu.ac.ir

**Web page address**

## Person responsible for scientific 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**

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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**