

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Evaluating the effects of Borageseed's oiloninflammatory on cytokines levels in acute respiratory distress syndrome (ARDS) patients

Protocol summary

Summary

The aim of this study is evaluation of effects of Borage seed's oil on inflammatory cytokines levels in acute respiratory distress syndrome (ARDS) patients. According to the Berlin, patients were diagnosed for acute respiratory distress syndrome, were enrolled. Patients with Liver diseases, blood coagulation disorders, gastrointestinal bleeding, inflammatory bowel disease, diarrhea and other gastrointestinal malignancies under Routine treatment of inflammatory diseases were excluded from the study. In a randomized clinical trial, 30patients in ICU were assigned randomly to receive 2 gr Borage seed extract or placebo (control group) for five days. Inflammatory cytokine levels causing acute respiratory distress syndrome, including CXCL-8 and TNF -a and IL -6 were measured to compare the two groups.

Email address

iran.criticalcare@yahoo.com

Recruitment status

Recruitment complete

Funding source

Shahid Beheshti University of Medical sciences

Expected recruitment start date

2013-01-01, 1391/10/12

Expected recruitment end date

2016-06-01, 1395/03/12

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016072420592N7**

Registration date: **2017-06-05, 1396/03/15**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-06-05, 1396/03/15

Registrant information

Name

Seyed Mohammad Reza Hashemian

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2610 9944

Scientific title

Evaluating the effects of Borageseed's oiloninflammatory on cytokines levels in acute respiratory distress syndrome (ARDS) patients

Public title

Evaluating the effects of Borageseed's oiloninflammatory in treatment of acute respiratory distress syndrome (ARDS) patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria: Patients with acute respiratory distress syndrome. Exclusion Criteria: Liver diseases; blood coagulation disorders;gastrointestinal bleeding; inflammatory bowel disease; diarrhea and other gastrointestinal malignancies under Routine treatment of inflammatory diseases

Age

From **16 years** old to **70 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

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Shahid Beheshti University of Medical Sciences

Street address

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

City

Tehran

Postal code

Approval date

2016-08-06, 1395/05/16

Ethics committee reference number

IR.SBMU.NRITLD.REC.1395.240

Health conditions studied

1

Description of health condition studied

Acute Respiratory Distress Syndrome (ARDS)

ICD-10 code

U04.9

ICD-10 code description

Severe acute respiratory syndrome [SARS], unspecified

Primary outcomes

1

Description

interlukin 8

Timepoint

In start of the study and 3th and 5th days.

Method of measurement

Human Boster Kit

Secondary outcomes

1

Description

Tumor necrosis factor alpha

Timepoint

In start of the study and 3th and 5th days

Method of measurement

Kit

Intervention groups

1

Description

Intervention: The patients in intervention group received
2 gr daily of Borage seed extract for 5 days.

Category

Treatment - Drugs

2

Description

Control: The patients in control group received 2 gr daily
of placebo for 5 days.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Masih Daneshvari Hospital

Full name of responsible person

Seyed Mohammadreza Hashemian

Street address

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

City

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Shahid Beheshti
University of Medical Sciences

Full name of responsible person

Mohammad Mehdi Sadoughi, investigator

Street address

Shahid Beheshti University of Medical Sciences,
Tabnak Street, Shahid Chamran Highway, Tehran,
Iran

City

Tehran

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice chancellor for research, Shahid Beheshti University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

empty

Person responsible for general inquiries**Contact****Name of organization / entity**

Masih Daneshvari Hospital

Full name of responsible person

Seyed Mohammadreza Hashemian

Position

Associate professor

Other areas of specialty/work**Street address**

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Web page address**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty