# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

28 Jun 2026

## An Investigation of the impact of Faramir containing Salvia officinalis leaf extract on the level of serum IL-6 in patients with COVID-19

## Protocol summary

**Study aim**
Determining the effectiveness of the natural product Faramir containing Salvia officinalis extract as antiviral and anti-inflammatory treatment in COVID-19 patients

**Design**
Two arm parallel group randomized double-blind controlled trial

**Settings and conduct**
Patients are recruitedn in Loghman Hospital and assigned in two parallel groups randomly.

**Participants/Inclusion and exclusion criteria**
Inclusion criteria: Covid-19 infection confirmed by positive PCR-viral load test Some or all of the symptoms include fever, fatigue, muscle aches (headache), headache, cough, chest tightness, and shortness of breath Need to be hospitalized Exclusion criteria: Malignant tumors and other acute systemic diseases Co-infection with HIV and tuberculosis History of asthma, asthma-like attacks and respiratory problems Life-threatening comorbidity Use of any other herbal substance Homofusion and plasmapheresis Drug allergy Need for hospitalization in the intensive care unit (ICU) Pregnancy Lactation

**Intervention groups**
Intervention group: Patients who receive natural product Faramir along with standard treatments. Control group: Patients who receive only standard treatments

**Main outcome variables**
Mortality rate, discharge duration and virus clearance

## General information

**Reason for update**

**Acronym**

**IRCT registration information**
IRCT registration number: **IRCT20170315033086N7**
Registration date: **2020-11-12, 1399/08/22**
Registration timing: **prospective**
Last update: **2020-11-12, 1399/08/22**
Update count: **0**

**Registration date**
2020-11-12, 1399/08/22

**Registrant information**

**Name**
Saeed Karima

**Name of organization / entity**
Shahid Beheshti University of Medical Sciences (SBMU)

**Country**
Iran (Islamic Republic of)

**Phone**
+98 21 9666 1028

**Email address**
karima@sbmu.ac.ir

**Recruitment status**
**Recruitment complete**

**Funding source**

**Expected recruitment start date**
2020-11-21, 1399/09/01

**Expected recruitment end date**
2022-01-21, 1400/11/01

**Actual recruitment start date**
empty

**Actual recruitment end date**
empty

**Trial completion date**
empty

**Scientific title**
An Investigation of the impact of Faramir containing Salvia officinalis leaf extract on the level of serum IL-6 in patients with COVID-19

**Public title**
An Investigation of the impact of Faramir on the clinical symptoms in patients with COVID-19

**Purpose**

Supportive

**Inclusion/Exclusion criteria**

**Inclusion criteria:**

Covid-19 infection confirmed by positive PCR-viral load test Some or all of the symptoms include fever, fatigue, muscle aches (headache), headache, cough, chest tightness, and shortness of breath Need to be hospitalized

**Exclusion criteria:**

Malignant tumors and other acute systemic diseases Co-infection with HIV and tuberculosis History of asthma, asthma-like attacks and respiratory problems Life-threatening comorbidity Use of any other herbal substance Homofusion and plasmapheresis Drug allergy Need for hospitalization in the intensive care unit (ICU) Pregnancy Lactation

**Age**

From **18 years** old to **75 years** old

**Gender**

Both

**Phase**

2

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **128**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Randomization is designed based on four-sized block randomization procedure. A non-ordered computer sequence list including the patient-assigned code and the order of recruitment is generated by an epidemiologist using Stata v.15. Given the block size of 4, there are 6 possible ways to equally assign participants to each treatment group. Therefore recruitment of participants to each treatment category is randomized and unpredictable. Following this randomization, an equal number of participants is randomly assigned to each treatment group.

**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 Shahid Beheshti University of Medical Sciences, School of Medicine

**Street address**

Ground floor, medical faculty, Koodakyar Alley, Daneshjoo Blvd, Velenjak, Tehran, Iran

**City**

Tehran

**Province**

Tehran

**Postal code**

1985717434

**Approval date**

2020-11-10, 1399/08/20

**Ethics committee reference number**

IR.SBMU.MSP.REC.1399.396

## Health conditions studied

### 1

**Description of health condition studied**

COVID-19

**ICD-10 code**

B34.2

**ICD-10 code description**

Coronavirus infection, unspecified

## Primary outcomes

### 1

**Description**

Survival rate

**Timepoint**

30 days after study commencement

**Method of measurement**

Deaths record

### 2

**Description**

Discharge duration

**Timepoint**

Hospitalization day and discharge day

**Method of measurement**

Record the number of hospitalization days

### 3

**Description**

virus clearance

**Timepoint**

At the commencement of the investigation and 8 days after taking

**Method of measurement**

Polymerase chain reaction (PCR)

### 4

**Description**

Serum Inflammatory Factors- Interleukin 6

**Timepoint**

At the beginning of the study and 8 days after the study commencement

**Method of measurement**

ELISA Method

## Secondary outcomes

### 1

**Description**
Serum Inflammatory Factors- c reactive protein (CRP)
**Timepoint**
At the beginning of the study and 8 days after the study commencement
**Method of measurement**
ELISA Method

### 2

**Description**
Serum Inflammatory Factors- Erythrocyte sedimentation rate (ESR)
**Timepoint**
At the beginning of the study and 8 days after the study commencement
**Method of measurement**
Western green method

## Intervention groups

### 1

**Description**
Intervention group: Patients who receive natural product Faramir containing Salvia officinalis extract (750 mg oral caplet, 6 times a day, every 4 hours and for 8 days) along with standard treatments.The active ingredient of the medicinal species of Ṡalvia officinali is prepared from the leaves of the medicinal species of the plant by Meem Pharmaceutical Factory and will be stored in closed containers in conditions away from light and moisture.
**Category**
Treatment - Drugs

### 2

**Description**
Control group: Patients who receive only standard treatments
**Category**
Other

## Recruitment centers

### 1

**Recruitment center**
**Name of recruitment center**
Loghman Hospital
**Full name of responsible person**
Minoosh Shabani
**Street address**
Makhsoos st., Lashgar junction
**City**
Tehran
**Province**
Tehran
**Postal code**
1333635445
**Phone**
+98 21 5541 9005
**Email**
minoosh.shabani@sbmu.ac.ir

## Sponsors / Funding sources

### 1

**Sponsor**
**Name of organization / entity**
Shahid Beheshti University of Medical Sciences
**Full name of responsible person**
Saeed Karima
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Velenjak, Kudakyar st.
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**Email**
karima@sbmu.ac.ir
**Grant name**
**Grant code / Reference number**
**Is the source of funding the same sponsor organization/entity?**
No
**Title of funding source**
Behbalin
**Proportion provided by this source**
100
**Public or private sector**
Private
**Domestic or foreign origin**
Domestic
**Category of foreign source of funding**
*empty*
**Country of origin**
**Type of organization providing the funding**
Other

## Person responsible for general inquiries

**Contact**
**Name of organization / entity**
Shahid Beheshti University of Medical Sciences
**Full name of responsible person**
Minoosh Shabani
**Position**
Assisstant professor
**Latest degree**
Specialist
**Other areas of specialty/work**
Infectious diseases

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## Person responsible for scientific inquiries

**Contact**
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Behbalin
**Full name of responsible person**
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**Position**
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**Other areas of specialty/work**
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## Person responsible for updating data

**Contact**
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**Email**
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## 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**
Not applicable
**Informed Consent Form**
Yes - There is a plan to make this available
**Clinical Study Report**
Not applicable
**Analytic Code**
Undecided - It is not yet known if there will be a plan to make this available
**Data Dictionary**
Not applicable
**Title and more details about the data/document**
collected de-identified IPD, IPD collected for the primary outcome measure only
**When the data will become available and for how long**
De-identified data will be available starting from April, 2025
**To whom data/document is available**
Academics employed at various research/university institutions and the industry.
**Under which criteria data/document could be used**
No specific condition are specified.
**From where data/document is obtainable**
Recruitment center
**What processes are involved for a request to access data/document**
1- The applicant would be asked to provide a written formal request letter, containing the importance of the data and the project processes. 2- Following the receipt of request letter, the data would be provided in no more than two weeks.
**Comments**