

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Aug 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 recruited 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 Salvia officinalis 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

Street address

Velenjak, Kudakyar st.

City

Tehran

Province

Tehran

Postal code

1333635445

Phone

+98 21 2243 9974

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

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Infectious diseases

Street address
Makhsos st., Lashgar junction
City
Tehran
Province
Tehran
Postal code
1333635445
Phone
+98 21 5541 9005
Email
minoosh.shabani@sbmu.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Behbalin
Full name of responsible person
Somayeh Mahmoodi Baram
Position
Assistant Professor
Latest degree
Ph.D.
Other areas of specialty/work
Biochemistry
Street address
Niyayesh Highway, Shahid Beheshti University of
Medical Sciences Incubator Center
City
تهران
Province
Tehran
Postal code
1996835113
Phone
+98 21 9666 1028
Email
info@behbalin.com

Person responsible for updating data

Contact

Name of organization / entity
Behbalin
Full name of responsible person
Somayeh Mahmoodi Baram
Position
Assistant Professor
Latest degree
Ph.D.
Other areas of specialty/work

Biochemistry
Street address
Niyayesh Highway
City
تهران
Province
Tehran
Postal code
1996835113
Phone
+98 21 9666 1028
Email
info@behbalin.com

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