Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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
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
Assisstant professor
Latest degree
Specialist
Other areas of specialty/work
Infectious diseases

Street address
Makhsoos 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