

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Evaluation of the effectiveness of Iranian Borage Aerial Part infusion on the management of Covid-19 mild to moderate symptoms: a clinical trial

Protocol summary

Study aim

Evaluation of the effectiveness of Iranian Borage Aerial Part infusion on the management of Covid-19 mild to moderate symptoms

Design

This clinical trial has a control group, and with parallel groups, double-blinded, randomized, phase 0, and is performed on 60 patients. The randomization method will be blocked randomization (Quaternary random blocks) using Random Allocation Software

Settings and conduct

This research will be conducted at Ali Asghar hospital in Shiraz, Iran. Sixty patients will be randomly located in one of two groups of the intervention or control groups. Patients in the intervention group will take the Iranian Borage Aerial Part infusion TID for 5 days in addition to the routine treatment for COVID-19. Patients in the control group will receive routine treatment and placebo. Routine blood tests and the need for intubation will be assessed. This is a double-blind trial and only the evaluator will know the results

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with COVID-19 confirmed by RT-PCR and Ground glass view on CT scan; Patients with COVID-19 symptoms who have been exposed to suspected people in the last 14 days; Having a conscious consent form signed to participate in the study; Not participating in similar studies at the same time
Exclusion criteria: People with a history of allergy to herbal medicines; Having liver, kidney, cardiovascular and endocrine diseases; Permanent use of psychiatric drugs; Pregnant and breastfeeding women; People who can't swallow

Intervention groups

Intervention groups will be two ones. Patients in the intervention group will receive Iranian Borage Aerial Part infusion in addition to the routine treatment, but in the control group, they will receive placebo in addition to the routine treatment.

Main outcome variables

Fever; Vital capacity; Respiratory status; WBC and platelet count; ESR; CRP

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201016049048N1**

Registration date: **2020-11-04, 1399/08/14**

Registration timing: **prospective**

Last update: **2020-11-04, 1399/08/14**

Update count: **0**

Registration date

2020-11-04, 1399/08/14

Registrant information

Name

Ali Sahragard

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 5422 5725

Email address

stud2460304560@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-11-07, 1399/08/17

Expected recruitment end date

2021-02-05, 1399/11/17

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Evaluation of the effectiveness of Iranian Borage Aerial Part infusion on the management of Covid-19 mild to moderate symptoms: a clinical trial

Public title
Effect of Iranian Borage on the management of Covid-19 symptoms

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Patients with COVID-19 confirmed by RT-PCR and Ground glass view on CT scan Patients with COVID-19 symptoms (such as fever, muscle pain, chest discomfort, cough, reduced CBC and platelets, increased CRP and ESR) who have been exposed to suspected people in the last 14 days Having a conscious consent form signed to participate in the study Not participating in similar studies at the same time
Exclusion criteria:
People with a history of allergy to herbal medicines Having liver, kidney and cardiovascular diseases Permanent use of psychiatric drugs Pregnant and breastfeeding women People who can't swallow Having endocrine diseases like diabetes

Age
From **18 years** old

Gender
Both

Phase
0

Groups that have been masked

- Participant
- Care provider
- Investigator
- Data analyser
- Data and Safety Monitoring Board

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
The randomization method will be blocked randomization (Quaternary random blocks). Randomization units are individuals. Sixty patients are randomly assigned to one of the two intervention and control groups using Random Allocation Software. This study is a double-blind method and patients in the intervention group will receive the intervention drug in addition to the routine treatment, but in the control group, they will receive the placebo in addition to the routine treatment.

Blinding (investigator's opinion)
Double blinded

Blinding description
The study will be a double-blind trial and only the evaluator knows the results and the code of the

intervention or control group. The containers of the drug and placebo are quite similar in appearance. The intervention and control groups will be separated by receiving a code.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Shiraz University of Medical Sciences
Street address
Zand street
City
Shiraz
Province
Fars
Postal code
7134814336

Approval date
2020-04-04, 1399/01/16

Ethics committee reference number
IR.SUMS.REC.1399.015

Health conditions studied

1

Description of health condition studied
corona virus (covid-19)

ICD-10 code
U07.1

ICD-10 code description
COVID-19, virus identified

Primary outcomes

1

Description
Fever

Timepoint
At the beginning and end of the study

Method of measurement
Digital thermometer

2

Description
Respiratory status

Timepoint

At the beginning and end of the study
Method of measurement
Observation

3

Description

White blood cell count

Timepoint

At the beginning and end of the study

Method of measurement

Blood sample test

4

Description

Platelet blood count

Timepoint

At the beginning and end of the study

Method of measurement

Blood sample test

5

Description

Erythrocyte Sedimentation Rate

Timepoint

At the beginning and end of the study

Method of measurement

Blood sample test

6

Description

C-reactive protein

Timepoint

At the beginning and end of the study

Method of measurement

Blood sample test

7

Description

Vital capacity

Timepoint

At the beginning and end of the study

Method of measurement

Observation

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Patients in the intervention group will receive Iranian Borage Aerial Part infusion (1 g/100 cc water) TID for 5 days in addition to the routine treatment.

Category

Treatment - Drugs

2

Description

Control group: Patients in the control group will receive the placebo (100 cc boiled water) TID for 5 days in addition to the routine treatment.

Category

Placebo

Recruitment centers

1

Recruitment center**Name of recruitment center**

Ali asghar hospital

Full name of responsible person

Mohammad Mehdi Zarshenas

Street address

Meshkinfam street

City

Shiraz

Province

Fars

Postal code

7143918796

Phone

+98 71 3228 8602

Fax

+98 71 3228 8907

Email

aliasghar@sums.ac.ir

Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

Shiraz University of Medical Sciences

Full name of responsible person

Dr. Abbas Rezaeian zadeh

Street address

Central building of Shiraz university of medical sciences, Zand Street

City

Shiraz

Province

Fars

Postal code

7134814336

Phone

+98 71 3230 5410

Email

info@sums.ac.ir

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Shiraz 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**

Shiraz University of Medical Sciences

Full name of responsible person

Mohammad mehdi Zarshenas

Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

Street address

Shiraz school of pharmacy, Karafrin Street

City

Shiraz

Province

Fars

Postal code

7146864685

Phone

+98 71 3242 4127

Email

zarm@sums.ac.ir

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

Shiraz University of Medical Sciences

Full name of responsible person

Mohammad mehdi Zarshenas

Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

Street address

Shiraz school of pharmacy, Karafrin Street

City

Shiraz

Province

Fars

Postal code

7146864685

Phone

+98 71 3242 4127

Email

zarm@sums.ac.ir

Person responsible for updating data**Contact****Name of organization / entity**

Shiraz University of Medical Sciences

Full name of responsible person

Ali Sahragard

Position

Student

Latest degree

A Level or less

Other areas of specialty/work

Medical Pharmacy

Street address

Shiraz school of pharmacy, Karafrin Street

City

Shiraz

Province

Fars

Postal code

7146864685

Phone

+98 71 3242 4127

Email

a.sahragard646@gmail.com

Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available