Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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
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Iran (Islamic Republic of)
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+98 71 5422 5725
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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

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Meshkinfam street

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Dr. Abbas Rezaeian zadeh

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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
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Person responsible for updating data

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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