

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Evaluating the efficacy of herbal capsule in COVID-19 patients in a clinical trial

Protocol summary

Study aim

Evaluating the efficacy of herbal products (capsule) in COVID-19 patients in a clinical trial

Design

A clinical trial with a control group, with parallel, randomized groups, phase 3 on 100 patients. For randomization, a table of random numbers based on Random Allocation software was used. Blinding was not possible.

Settings and conduct

100 patients will be selected according to the national guidelines for diagnosis and treatment of COVID-19 disease that require hospitalization, and 50 patients receive routine treatment and 50 patients receive herbal treatment (capsule every 12 hours) along with routine treatment for 1 week. With the simple randomization method and based on the table of random numbers, it will be divided into two groups and one

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients of both sexes in the age range of 18 to 75 years, who require hospitalization according to the national guidelines for diagnosis and treatment of COVID-19, and have completed an informed consent form to enter the study. Exclusion criteria: pregnancy and lactation, the presence of any history of allergy to any of the components of the herbal product, the patient's inability to take oral form, the patient's involvement in any serious concomitant underlying diseases, including hypertension, heart disease, lung disease, Brain disease, and diabetes.

Intervention groups

In the control group, 50 patients received routine supportive interventions and standard COVID-19 treatment regimen based on the Ministry of Health protocol, including hydroxychloroquine at a dose of 200 mg twice daily. In the intervention group, 50 patients receive a capsule containing herbal products every 12 hours for 1-week in addition to standard COVID-19 treatment based on the Ministry of Health protocol.

Main outcome variables

Temperature; Respiratory rate; cough, dyspnea, O2 saturation, WBC count

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200330046899N1**

Registration date: **2020-06-17, 1399/03/28**

Registration timing: **registered_while_recruiting**

Last update: **2020-06-17, 1399/03/28**

Update count: **0**

Registration date

2020-06-17, 1399/03/28

Registrant information

Name

Mohammad Setayesh

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-04-20, 1399/02/01

Expected recruitment end date

2020-07-22, 1399/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Evaluating the efficacy of herbal capsule in COVID-19 patients in a clinical trial

Public title
Effectiveness of herbal capsule in COVID-19

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Patients who require hospitalization based on national guidelines for diagnosis and treatment of COVID-19 and need to start drugs. 18 to 75 years of age for both sexes
The patient's ability to fill out an informed consent form to enter the study
Exclusion criteria:
Pregnancy and lactation History of allergy to any of the components of the herbal product The patient's inability to take oral form The patients with serious underlying disease at the same time, including high blood pressure, heart disease, lung disease, cerebral disease, diabetes.

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

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **50**

Randomization (investigator's opinion)
Randomized

Randomization description
Block randomization method is used in this study. The treatment assignment is in a 1:1 ratio, and there are two groups, then, the block size is chosen 4. Possible balanced combinations are calculated with 2 subjects in control and 2 subjects in the intervention group (Six possibilities). In each 4 block size, two patients will be assigned to the intervention (capsule) group and two patients will be assigned to the control group. To allocate all participants in the two groups, the blocks are randomly selected.

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

Kerman University of Medical Science

Street address

Beginning of Ibn Sina Street, Beginning of Jihad Blvd., Somayeh Road (Tahmasebabad), Kerman

City

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Province

Kerman

Postal code

7616913555

Approval date

2020-04-13, 1399/01/25

Ethics committee reference number

IR.KMU.REC.1399.055

Health conditions studied

1

Description of health condition studied

COVID-19

ICD-10 code

U07.1

ICD-10 code description

COVID-19

Primary outcomes

1

Description

Temperature

Timepoint

0-1-2-3-4-5-6-7 days after starting intervention

Method of measurement

Mercury thermometer

2

Description

Cough severity

Timepoint

1th and 7th dady after starting intervention

Method of measurement

cough severity score 1-4

3

Description

Respiratory rate

Timepoint

0-1-2-3-4-5-6-7 days after starting intervention

Method of measurement

Counting the number of breaths per minute

4

Description

Dyspnea severity

Timepoint

0-1-2-3-4-5-6-7 days after starting intervention

Method of measurement

Dyspnea severity score 1-4

5

Description

O2 saturation percentage

Timepoint

pulse oximetry at baseline, 1-2-3-4-5-6-7 days after starting intervention

Method of measurement

pulse oximeter

6

Description

white blood cell count

Timepoint

baseline and day 7 after starting intervention

Method of measurement

WBC counting under the microscope

Secondary outcomes

empty

Intervention groups

1

Description

Control group: 50 patients receive routine interventions according to the instructions of the Ministry of Health for 1 weeks

Category

Treatment - Drugs

2

Description

Intervention group: 50 patients receive herbal treatment including capsule (Lyophilized powder from hydroalcoholic 70% extracts of Punica granatum L., Rheum palmatum L., Glycyrrhiza glabra L., and seed powder of Nigella sativa L.) 2 times a day with routine interventions based on the instructions of the Ministry of Health for 1 weeks.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center**Name of recruitment center**

Afzalipoor Hospital

Full name of responsible person

Mohammad Seatyesh

Street address

Imam Khomeini Highway, Afzalipoor hospital

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Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

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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

Kerman 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**

Kerman University of Medical Sciences
Full name of responsible person
Dr. Hamid Aboosaeidi
Position
Assistant Professor
Latest degree
Specialist
Other areas of specialty/work
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Person responsible for updating data

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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

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All results will be shared with identified individuals

When the data will become available and for how long

Start the access period from 6 months after printing results

To whom data/document is available

Academic researchers can access data

Under which criteria data/document could be used

For use in review articles, and modeling can be used in other studies.

From where data/document is obtainable

for data accessing, send an email to msetayeshmail@gmail.com. Or call 09133950546

What processes are involved for a request to access data/document

It will be done through coordination with the executor or the vice chancellor for research of the university and after the identification of the applicant.

Comments