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

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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

Kerman

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
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Sponsors / Funding sources

1

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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
Infectious diseases

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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 mseteyeshmail@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