# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

08 Nov 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)

**Phone**
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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**
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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**
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Kerman University of Medical Sciences

**Full name of responsible person**
Dr. Hamid Aboosaeidi

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Assistant Professor

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## Person responsible for scientific inquiries

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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**