

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

30 May 2026

### Formulation and evaluation of their efficacy of herbal capsule and decoction in patients with COVID-19 via a randomized clinical trial.

#### Protocol summary

##### Study aim

Preparation of two oral herbal remedies including decoction and capsule and evaluation of their efficacy in patients with COVID-19 via a randomized clinical trial.

##### Design

Randomized Concurrent Controlled Trial

##### Settings and conduct

68 patients are selected based on national guidelines for diagnosis and treatment of COVID-19 requiring hospitalization and drug treatment. Thirty-four patients receive routine treatment, and 34 receive herbal remedies (decoction every 8 hours and capsules every twelve hours) plus routine treatment for 2 weeks. To randomly assign the patients to two groups of treatment and placebo by a third person and using a computer program with simple randomization method, the random sample number is generated and each patient will be assigned a number.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: 1. Patients with one or more of the following symptoms in addition to acute respiratory disease (ARI): • RR > 30 • PO<sub>2</sub> < 93% • Pulmonary infiltration in chest x-ray 2. Age range of 18 to 75 years in both genders 3. Patient not intubated. 4. Lack of any serious concomitant disease of the heart, brain, or lungs, metabolic disorders, and etc. Exclusion criteria: 1. Pregnancy and lactation 2. Any history of allergy to any of the herbal product components 3. Inability to take a drug per-oral 4. Need for intubation 5. Any condition that precludes continuance of medical intervention based on the judgment of a physician.

##### Intervention groups

34 patients receive routine interventions according to the instructions of the Ministry of Health and 34 patients receive herbal treatment (decoction every 8 hours and capsule every 12 hours) with routine interventions based on the instructions of the Ministry of Health for 2 weeks.

##### Main outcome variables

The rate of radiologic improvement in chest x-ray or CT

scan based on expert evaluation

#### General information

##### Reason for update

In the intervention section, examples of drug components were given, which according to the project executors, for perfect conformity with approved proposal and the ongoing project, components were completed with supplemented corrections.

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20180712040449N2**  
Registration date: **2020-04-01, 1399/01/13**  
Registration timing: **registered\_while\_recruiting**

Last update: **2020-04-28, 1399/02/09**

Update count: **1**

##### Registration date

2020-04-01, 1399/01/13

##### Registrant information

###### Name

Samaneh Soleymani

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 8899 3656

###### Email address

S\_Soleymani@razi.tums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-03-23, 1399/01/04

##### Expected recruitment end date

2020-06-18, 1399/03/29

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Formulation and evaluation of their efficacy of herbal capsule and decoction in patients with COVID-19 via a randomized clinical trial.

**Public title**

Effect of oral multi-herbal preparation on COVID-19

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Patients with one or more of the following symptoms in addition to acute respiratory disease (ARI):• RR> 30• PO2 <93%• Pulmonary infiltration in chest x-ray• Clinical judgment of a specialist Age range of 18 to 75 years in both genders Lack of any serious concomitant disease of the heart, brain, or lungs, metabolic disorders, and etc. The patient's ability and own will to fill out a personal consent form for inclusion in the study Patient not intubated.

**Exclusion criteria:**

Pregnancy and lactation Any history of allergy to any of the herbal product components Inability to take a drug per-oral Any condition that precludes continuance of medical intervention based on the judgment of a physician. Need for intubation Nausea and vomiting and oral intolerance Resistant hypoxemia Reduced level of consciousness Hemodynamic instability Hypercapnia - respiratory fatigue Any manifestation of known side effects of any of the herbal product components

**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: **68**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

To randomly assign the patients to two groups of treatment and placebo by a third person and using a computer program with simple randomization method, the random sample number is generated and each patient will be assigned a number.

**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**

Vice-Chancellor in Research Affairs of Tehran University of Medical Sciences

**Street address**

Vice-Chancellor in Research Affairs of Tehran University of Medical Sciences, Ghods Ave, Keshavarz Blvd, Tehran

**City**

Tehran

**Province**

Tehran

**Postal code**

1419814171

**Approval date**

2020-03-22, 1399/01/03

**Ethics committee reference number**

IR.TUMS.VCR.REC.1399.024

**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**

O2 saturation percentage

**Timepoint**

Clinical examination and pulse oximetry at baseline, days 3, 6, 9, 12 and 14

**Method of measurement**

Pulse Oximeter

**2****Description**

Lung inflammation

**Timepoint**

CT scan at baseline, days 7 and 14

**Method of measurement**

CT scan

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: 34 patients receive herbal treatment including 150 ml of decoction (Matricaria chamomilla L., Zataria multiflora Boiss., Glycyrrhiza glabra L., Ziziphus jujuba Mill., Ficus carica L., Urtica dioica L., Althaea officinalis L., Hyssopus officinalis L.) 3 times a day and capsule (Lyophilized powder from hydroalcoholic 70% extracts of Punica granatum L., Rheum palmatum 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 2 weeks.

#### Category

Treatment - Drugs

### 2

#### Description

Control group: 34 patients receive routine interventions according to the instructions of the Ministry of Health for 2 weeks.

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Shohada Pakdasht Specialty and Subspecialty Hospital

##### Full name of responsible person

Mehrdad Karimi

##### Street address

25 km of Khavaran Road., Pakdasht

##### City

Pakdasht

##### Province

Tehran

##### Postal code

1983963113

##### Phone

+98 21 3644 2012

##### Email

shpmc@sbmu.ac.ir

### 2

#### Recruitment center

##### Name of recruitment center

Shohada Gomnam Specialty and Subspecialty Hospital

##### Full name of responsible person

Mehrdad Karimi

##### Street address

Khorasan Sq., Khavaran St.

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##### Province

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##### Postal code

shgm-hospital@sbmu.a

##### Phone

+98 21 3630 2008

##### Email

shgm-hospital@sbmu.ac.ir

### 3

#### Recruitment center

##### Name of recruitment center

Imam Khomeini Hospital Complex

##### Full name of responsible person

Mehrdad Karimi

##### Street address

Dr Gharib St., Keshavarz Blvd

##### City

Tehran

##### Province

Tehran

##### Postal code

۱۴۱۹۷۳۳۱۴۱

##### Phone

+98 21 6119 0000

##### Email

Imamhospital@tums.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Tehran University of Medical Sciences

##### Full name of responsible person

Mohammad Ali Sahraian

##### Street address

Vice-Chancellor in Research Affairs of Tehran University of Medical Sciences, Ghods Ave, Keshavarz Blvd

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##### Province

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##### Postal code

1417653761

##### Phone

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##### Email

rcco@tums.ac.ir

#### Grant name

#### Grant code / Reference number

#### Is the source of funding the same sponsor organization/entity?

Yes

#### Title of funding source

Tehran 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**

Tehran University of Medical Sciences

**Full name of responsible person**

Mehrdad Karimi

**Position**

Associate Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Traditional Medicine

**Street address**

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**Full name of responsible person**

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**Position**

Associate Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

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**Email**

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

Tehran University of Medical Sciences

**Full name of responsible person**

Samaneh Soleymani

**Position**

PhD candidate student

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Medical Pharmacy

**Street address**

No. 27, Sarparast Ave, Taleghani Ave, Tehran, School of Persian medicine

**City**

Tehran

**Province**

Tehran

**Postal code**

1419814171

**Phone**

+98 21 8897 6527

**Email**

s.soleymani84@gmail.com

**Web page address**<http://stpm.tums.ac.ir/>**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**

Undecided - It is not yet known if there will be 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**

The documentation including the primary and secondary outcomes of patients that will be available

**When the data will become available and for how long**

From the start of the clinical study to one year after the completion of the clinical study

**To whom data/document is available**

If another researcher wants to perform a clinical study in this field and needs our information to do the study, the information will be provided with confidentiality. - If

patients have side effects, and their doctors need the treatment information. -If a health authority's health policy requires our study information, then the information is provided with confidentiality.

**Under which criteria data/document could be used**

If the applicant is authenticated, his request will be discussed with other researchers involved in the study, and the result will be informed to him.

**From where data/document is obtainable**

Mehrdad Karimi mehrdadkarimi@yahoo.com 0098 21 66976527

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

At first, the applicants must send their request to the correspond author of the study, whose email address is on the IRCT site, and after verifying the applicant's identity, including one of the upon items, the correspond author requests information of the researchers who are present in the study and is sent to applicants. This period, after the applicant's authentication, will take about two weeks.

**Comments**