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 • PO2 <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 executers, 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)

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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 officinali 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
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1983963113
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2

Recruitment center
Name of recruitment center
Shohada Gomnam Specialty and Subspecialty Hospital
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3

Recruitment center
Name of recruitment center
Imam Khomeini Hospital Complex
Full name of responsible person
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
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1417653761
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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
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Other areas of specialty/work
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Person responsible for updating data

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Latest degree
Ph.D.
Other areas of specialty/work
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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