# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

02 Nov 2026

## Effect evaluation of herbal supplementation from the combination of sugarcane, black myrobalan and mastic along with the treatment protocol of the Ministry of Health on the course of COVID-19 disease

## Protocol summary

**Study aim**
Reduce the duration of treatment Disease severity phase prevention

**Design**
Clinical trial with control group, with parallel intervention, double-blind, randomized

**Settings and conduct**
In Peymaniyeh Hospital of Jahrom, in two groups of intervention and control as follows: Intervention group: Receiver of herbal supplements from a combination of black myrobalan and mastic and sugarcane along with the treatment protocol approved by the Ministry of Health. Control group: Receiver of treatment protocol approved by the Ministry of Health and placebo. The distribution of herbal supplements in the intervention group and placebo in the control group will be done by nurses based on the randomization result announced by the head nurse. The researcher and nurses will not know the randomization results and the type of package that are being given to the patient. The researcher should only provide the necessary supplement for the intervention and provide it to the head nurse.

**Participants/Inclusion and exclusion criteria**
Study participation criteria: • All patients admitted with a diagnosis of COVID-19 • COVID-19 patients who are willing to participate in study • The patient should not be among high-risk groups, such as breastfeeding or pregnant or etc. • Age> 18 years old • The patient does not have a specific underlying disease. Study exclusion criteria: • Dissatisfaction with continuing with herbal supplements treatment • herbal supplements Intolerance (in case of allergies and other similar cases) • After admission to the ICU • Positive pregnancy test

**Intervention groups**
Herbal supplement taking group (35 people). Placebo taking group (35 people)

**Main outcome variables**
Chest CT scan findings; Erythrocyte sedimentation rate; C-Reactive Protein; Clinical signs

## General information

**Reason for update**
Increase sample size

**Acronym**

**IRCT registration information**
IRCT registration number: **IRCT20200415047082N1**
Registration date: **2020-04-21, 1399/02/02**
Registration timing: **prospective**

Last update: **2020-12-02, 1399/09/12**
Update count: **1**

**Registration date**
2020-04-21, 1399/02/02

**Registrant information**

**Name**
esmail rayat dost

**Name of organization / entity**

**Country**
Iran (Islamic Republic of)

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+98 71 5427 7145

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e.rayatdost@jums.ac.ir

**Recruitment status**
**Recruitment complete**

**Funding source**

**Expected recruitment start date**
2020-05-04, 1399/02/15

**Expected recruitment end date**
2020-06-04, 1399/03/15

**Actual recruitment start date**
empty

**Actual recruitment end date**
empty
**Trial completion date**
empty

**Scientific title**
Effect evaluation of herbal supplementation from the combination of sugarcane, black myrobalan and mastic along with the treatment protocol of the Ministry of Health on the course of COVID-19 disease

**Public title**
Effect evaluation of herbal supplementation from the combination of sugarcane, black myrobalan and mastic along with the treatment protocol of the Ministry of Health on the course of coronavirus disease
**Purpose**
Supportive
**Inclusion/Exclusion criteria**
**Inclusion criteria:**
All patients admitted with a diagnosis of COVID-19 COVID-19 patients who are willing to participate in study The patient should not be among high-risk groups, such as breastfeeding or pregnant or etc. Age> 18 years old The patient does not have a specific underlying disease Study
**Exclusion criteria:**
People who are under 18 years of age People who are among the high-risk group People who have a specific underlying disease People who are characterized as severe in the illness course
**Age**
From **18 years** old
**Gender**
Both

**Phase**
2-3
**Groups that have been masked**

- Participant
- Investigator
- Outcome assessor

**Sample size**
Target sample size: **70**
**Randomization (investigator's opinion)**
Randomized
**Randomization description**
Randomization method: Simple randomization Randomization unit: individual Randomization tool: from random number table by assigning a code to each patient by the head nurse Allocation concealment: The distribution of herbal supplements in the intervention group and placebo in the control group will be done by nurses based on the randomization result announced by the head nurse. The researcher and nurses will not know the randomization results and the type of package that are being given to the patient. The researcher should only provide the necessary supplement for the intervention and provide it to the head nurse.
**Blinding (investigator's opinion)**
Double blinded
**Blinding description**
The distribution of herbal supplements in the intervention group and placebo in the control group will be done by nurses based on the randomization result announced by the head nurse. The researcher and nurses will not know the randomization results and the type of package that are being given to the patient. The researcher should only provide the necessary supplement for the intervention and provide it to the head nurse.
**Placebo**
Used
**Assignment**
Parallel
**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**
**Name of ethics committee**
Ethics committee of Jahrom University of Medical Sciences
**Street address**
Jahrom University of Medical Sciences, Shahid Motahari Ave.
**City**
Jahrom
**Province**
Fars
**Postal code**
7414846199
**Approval date**
2020-04-14, 1399/01/26
**Ethics committee reference number**
IR.JUMS.REC.1399.003

## Health conditions studied

### 1

**Description of health condition studied**
New Corona virus disease 2019
**ICD-10 code**
U07.1
**ICD-10 code description**
new Corona virus disease 2019

## Primary outcomes

### 1

**Description**
Symptoms of disease
**Timepoint**
During the hospital stay, on a daily basis
**Method of measurement**
The severity of patient's clinical symptoms is measured

on the basis of visual analog scale.

**2**

**Description**
Vital Signs
**Timepoint**
During the hospital stay, on a daily basis
**Method of measurement**
Vital signs monitoring device

**3**

**Description**
C-Reactive Protein
**Timepoint**
During the hospital stay, on a daily basis
**Method of measurement**
C-Reactive Protein test

## Secondary outcomes

**1**

**Description**
Pulmonary damages after illness
**Timepoint**
At the beginning of the study and 14 and 30 days after taking herbal supplements
**Method of measurement**
Chest Computed Tomography Scan

## Intervention groups

**1**

**Description**
Intervention group: Treatment protocol approved by the Ministry of Health during the period of hospitalization + herbal supplement taking from a combination of black myrobalan and mastic and of sugarcane twice a day without water during the period of hospitalization.
**Category**
Treatment - Drugs

**2**

**Description**
Control group: Treatment protocol approved by the Ministry of Health during the period of hospitalization + Placebo taking twice a day Without water during the period of hospitalization.
**Category**
Placebo

## Recruitment centers

**1**

**Recruitment center**
**Name of recruitment center**
Peymanieh hospital
**Full name of responsible person**
Rahim Raufi
**Street address**
Vali-e-Asr Ave., Peymaniyeh Hospital
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## Sponsors / Funding sources

**1**

**Sponsor**
**Name of organization / entity**
Jahrom University of Medical Sciences
**Full name of responsible person**
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solhjouk@yahoo.com
**Grant name**
**Grant code / Reference number**
**Is the source of funding the same sponsor organization/entity?**
Yes
**Title of funding source**
Jahrom 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**
Jahrom University of Medical Sciences
**Full name of responsible person**

Alireza Hashemi shiri

**Position**
Extern

**Latest degree**
A Level or less

**Other areas of specialty/work**
General Practitioner

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Shahid Motahari Ave., University of Medical Sciences, Research Unit

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## Person responsible for scientific inquiries

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Associate professor

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## Person responsible for updating data

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**Other areas of specialty/work**
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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**
Not applicable

**Title and more details about the data/document**
All potential data will be shared after people get unrecognizable

**When the data will become available and for how long**
Start of access period from 1399

**To whom data/document is available**
For public

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

**From where data/document is obtainable**
for public

**What processes are involved for a request to access data/document**
by requesting from corresponding writer

**Comments**