

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

19 Jun 2026

### Investigating the effect of Lavender (*Lavandula angustifolia* L.) syrup on improving the severity of cough in patients with definite or highly suspicious COVID-19

#### Protocol summary

##### Study aim

Investigating Lavender syrup efficacy to improve cough severity in definite or highly suspected COVID-19 patients

##### Design

Clinical trial with control group; with parallel groups; not blinded; randomized; phase 3 on 30 patients. Blocks of size 4 was used for randomization.

##### Settings and conduct

The study site is Kordkuy Amir-al-Momenin hospital affiliated to Golestan University of Medical Sciences.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Detection of mild to moderate COVID19. Non-inclusion criteria: Need to be hospitalized; Sensitivity to lavender.

##### Intervention groups

Both groups receive supportive therapies based on conventional classical medicine protocols. Patients in the intervention group will be given lavender syrup twice a day for 2 weeks. Patients in the control group will not be prescribed any medication other than routine treatments.

##### Main outcome variables

Respiratory rate; Cough; Lethargy; body pain; Fever; Satisfaction with treatment; Anxiety

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20110907007511N4**

Registration date: **2020-07-25, 1399/05/04**

Registration timing: **registered\_while\_recruiting**

Last update: **2020-07-25, 1399/05/04**

Update count: **0**

##### Registration date

2020-07-25, 1399/05/04

##### Registrant information

###### Name

Marzieh Qaraaty

###### Name of organization / entity

Golestan University of Medical sciences

###### Country

Iran (Islamic Republic of)

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###### Email address

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##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-05-16, 1399/02/27

##### Expected recruitment end date

2020-09-17, 1399/06/27

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Investigating the effect of Lavender (*Lavandula angustifolia* L.) syrup on improving the severity of cough in patients with definite or highly suspicious COVID-19

##### Public title

Effect of Lavender syrup on COVID-19

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

**Inclusion criteria:**

Age between 18 and 65 years  
 Conscious consent to participate in the study  
 Fever greater than 38 degrees or a feeling of hot flashes with at least one clinical sign of a dry cough, 24% number of breaths per minute, headache or body aches, feeling weak and lethargic, anosmia (olfactory disturbance) or taste disturbances, nausea  
 Seven days or less after the onset of symptoms at the first visit or relapse within 6 weeks of previous treatment  
 Absence of respiratory distress  
 Candidate for outpatient treatment

**Exclusion criteria:**

Need to be hospitalized  
 Pregnancy and lactation  
 Smoking  
 Underlying heart / liver /kidney disease / high blood pressure  
 Use other herbal medicines to control the symptoms of the disease  
 Sensitivity to lavender

**Age**

From **18 years** old to **65 years** old

**Gender**

Both

**Phase**

3

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **30**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Randomization: According to the random list resulting from block randomization using blocks of size 4 is done.

**Blinding (investigator's opinion)**

Not blinded

**Blinding description****Placebo**

Not used

**Assignment**

Parallel

**Other design features**

Fall criteria: - Sensitivity to lavender - Lack of proper use of prescribed drugs (less than 80%) - Drug side effects - Exacerbation of symptoms and the need for hospitalization

**Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics Committee of Golestan University of Medical Sciences

**Street address**

Shadravan Falsafi Higher Education Complex; at the beginning of Shast Kola road

**City**

Gorgan

**Province**

Golestan

**Postal code**

14395-477

**Approval date**

2020-05-03, 1399/02/14

**Ethics committee reference number**

IR.GOUMS.REC.1399.025

**Health conditions studied****1****Description of health condition studied**

COVID-19

**ICD-10 code**

U07.1

**ICD-10 code description**

COVID-19, virus identified

**2****Description of health condition studied**

COVID-19

**ICD-10 code**

U07.2

**ICD-10 code description**

COVID-19, virus not identified

**Primary outcomes****1****Description**

Changes in the severity of cough

**Timepoint**

Follow-up of patients in zero step (at the beginning of the study as a face-to-face visit), the first step (7 days after entering the study by telephone follow-up), the second step (14 days after entering the study by telephone follow-up), the third time (21 days after entering the study by telephone follow-up), the fourth time (14 days after the end of the study by telephone follow-up) and the fifth time (28 days after the end of the study by telephone follow-up)

**Method of measurement**

Checklist of patient and disease characteristics, satisfaction with treatment by asking general questions, assessment of patient symptoms based on Visual Analogue Scale (10 points)

**2****Description**

Changes in the severity of fever

**Timepoint**

Follow-up of patients in zero step (at the beginning of the study as a face-to-face visit), the first step (7 days after entering the study by telephone follow-up), the second step (14 days after entering the study by telephone follow-up), the third time (21 days after entering the study by telephone follow-up), the fourth time (14 days after the end of the study by telephone follow-up) and

the fifth time (28 days after the end of the study by telephone follow-up)

#### **Method of measurement**

Checklist of patient and disease characteristics, satisfaction with treatment by asking general questions, assessment of patient symptoms based on Visual Analogue Scale (10 points)

### **3**

#### **Description**

Change in the severity of shortness of breath

#### **Timepoint**

Follow-up of patients in zero step (at the beginning of the study as a face-to-face visit), the first step (7 days after entering the study by telephone follow-up), the second step (14 days after entering the study by telephone follow-up), the third time (21 days after entering the study by telephone follow-up), the fourth time (14 days after the end of the study by telephone follow-up) and the fifth time (28 days after the end of the study by telephone follow-up)

#### **Method of measurement**

Checklist of patient and disease characteristics, satisfaction with treatment by asking general questions, assessment of patient symptoms based on Visual Analogue Scale (10 points)

## **Secondary outcomes**

### **1**

#### **Description**

Quality of Life

#### **Timepoint**

Follow-up of patients in zero step (at the beginning of the study as a face-to-face visit), the first step (7 days after entering the study by telephone follow-up), the second step (14 days after entering the study by telephone follow-up), the third time (21 days after entering the study by telephone follow-up), the fourth time (14 days after the end of the study by telephone follow-up) and the fifth time (28 days after the end of the study by telephone follow-up)

#### **Method of measurement**

Short questionnaire 12 questions SF12

### **2**

#### **Description**

Satisfaction with treatment

#### **Timepoint**

Follow-up of patients in zero step (at the beginning of the study as a face-to-face visit), the first step (7 days after entering the study by telephone follow-up), the second step (14 days after entering the study by telephone follow-up), the third time (21 days after entering the study by telephone follow-up), the fourth time (14 days after the end of the study by telephone follow-up) and the fifth time (28 days after the end of the study by telephone follow-up)

#### **Method of measurement**

Asking general questions

### **3**

#### **Description**

Anxiety

#### **Timepoint**

Follow-up of patients in zero step (at the beginning of the study as a face-to-face visit), the first step (7 days after entering the study by telephone follow-up), the second step (14 days after entering the study by telephone follow-up), the third time (21 days after entering the study by telephone follow-up), the fourth time (14 days after the end of the study by telephone follow-up) and the fifth time (28 days after the end of the study by telephone follow-up)

#### **Method of measurement**

Based on the Hamilton Questionnaire

## **Intervention groups**

### **1**

#### **Description**

Intervention group: Supportive treatments related to the control of fever, pain, cough and other symptoms will be prescribed according to the common COVID-19 protocols in classical medicine. Also, in the intervention group receive 9 mL of lavender syrup twice a day for 14 days in addition to routine treatments (18 mL daily). Lavender syrup is prepared as follows: 100 g of dried lavender branch (*Lavandula angustifolia* L.) is washed, then soaked in 1000 mL of water for 3 hours. It is then boiled for 10 min and the resulting liquid is cooled in the laboratory. After cooling, the contents of the container are concentrated with a smooth filter and the resulting product is concentrated. From the obtained dry extract, we make 5 g to 100 g using the USP syrup making model with 66.7 g of honey and 28.5 g of water. The resulting syrup is poured into 120 mL sterile jars, sealed and sterilized by autoclave.

#### **Category**

Treatment - Drugs

### **2**

#### **Description**

Control group: Supportive treatments related to the control of fever, pain, cough and other symptoms will be prescribed according to the common COVID-19 protocols in classical medicine.

#### **Category**

Treatment - Drugs

## **Recruitment centers**

### **1**

#### **Recruitment center**

##### **Name of recruitment center**

Golestan Medical Sciences Hospitals

##### **Full name of responsible person**

Dr. Marzieh Qaraati  
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Shastkola Road  
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## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**  
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Dr.qaraati@goums.ac.ir  
**Grant name**  
**Grant code / Reference number**  
**Is the source of funding the same sponsor organization/entity?**  
Yes  
**Title of funding source**  
Gorgan 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**

Gorgan University of Medical Sciences  
**Full name of responsible person**  
Dr. Marzieh Qaraati  
**Position**  
Assistant Professor  
**Latest degree**  
Ph.D.  
**Other areas of specialty/work**  
Traditional Medicine  
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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)**

No - There is not a plan to make this available

**Justification/reason for indecision/not sharing IPD**

There is no further information

**Study Protocol**

No - There is not a plan to make this available

**Statistical Analysis Plan**

No - There is not a plan to make this available

**Informed Consent Form**

No - There is not a plan to make this available

**Clinical Study Report**

No - There is not a plan to make this available

**Analytic Code**

No - There is not a plan to make this available

**Data Dictionary**

No - There is not a plan to make this available