

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

07 Aug 2022

### Evaluation of the effectiveness of dietary plan for pulmonary diseases based on Persian medicine in patients infected with COVID-19

#### Protocol summary

##### Study aim

Evaluation of the effectiveness of dietary plan for pulmonary diseases based on traditional Iranian medicine in patients with COVID-19

##### Design

Patients enter the study based on the rooms. This means that the number of special rooms in the hospital is randomly assigned to the Persian medicine diet. Also in the control group, other rooms are considered as the usual diet group. During the study, all patients who will randomly hospitalize in the designated rooms will assign to a Persian or conventional medicine diet. Sample size to compare O2 saturation changes in two groups and for 4 repetitions to detect an effect size of 0.2, a first type error 0.05 and power 80% using G \* Power 3.1.9.2 software and to test repeated measure, within -between interaction is calculated and equal to 36 people in each group. Taking into account the 10% drop during the study, 40 people are considered for each group. A total of 80 people will enter the study.

##### Settings and conduct

This study is a randomized clinical trial in patients with an acute respiratory infectious disease caused by COVID19. Patients admitted to the wards of Shaaban 3ed hospital in Damavand will randomly assign to study.

##### Participants/Inclusion and exclusion criteria

Patients will be included in the study if they meet the "inclusion criteria for the clinical or paraclinical diagnosis of pulmonary infection due to acute pulmonary infection of COVID19" and do not have "exclusion criteria including respiratory intubation, oral intolerance, decreased level of consciousness, etc."

##### Intervention groups

Intervention group: The diet of lung diseases based on Persian medicine references for patients control group: The usual diet in public hospitals according to the instructions of the Ministry of Health

##### Main outcome variables

O2 saturation rate Duration of Hospitalization duration of

fever Cough duration

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20200105046009N4**

Registration date: **2020-07-18, 1399/04/28**

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

Last update: **2020-07-18, 1399/04/28**

Update count: **0**

##### Registration date

2020-07-18, 1399/04/28

##### Registrant information

##### Name

Seyyed Ali Mozaffarpur

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 11 3219 4728

##### Email address

dr.mozaffarpur@mubabol.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-06-30, 1399/04/10

##### Expected recruitment end date

2020-12-20, 1399/09/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

### Scientific title

Evaluation of the effectiveness of dietary plan for pulmonary diseases based on Persian medicine in patients infected with COVID-19

### Public title

management of the pulmonary diseases based on Persian medicine in patients infected with COVID-19

### Purpose

Treatment

### Inclusion/Exclusion criteria

#### Inclusion criteria:

Patients who have one / more of the following symptoms in addition to acute respiratory disease (ARI): • RR> 30 • PO<sub>2</sub> <93% • Pulmonary infiltration in chest radiography • Clinical judgment of a specialist doctor Age range 18 to 75 years of both gender The patient's ability and personal desire to fill out the personal consent form to enter the study

#### Exclusion criteria:

any chronic uncontrolled cardiac, renal, metabolic concomitant, etc. The patient with intubation. Nausea and vomiting and oral intolerance Treatment-resistant hypoxemia Decreased level of consciousness Hemodynamic instability

### 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: **80**

### Randomization (investigator's opinion)

Randomized

### Randomization description

Cluster Randomization will be done. In this way, the patients' hospital rooms are considered as clusters. In the hospitals, 16 beds in 4 rooms (preferably in 4-bed rooms) are allocated for study. The process of admitting patients and assigning them to beds is completely random and no choice will be made. In the hospital, 8 beds are randomly assigned to the traditional medicine diet and 8 beds to the standard diet. The selection and assignment of rooms to the diet are random and using a random digit table.

### 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

Ethics committee of Babol university of medical sciences

##### Street address

Ganjafrooz Street

##### City

Babol

##### Province

Mazandaran

##### Postal code

4717647745

#### Approval date

2020-06-28, 1399/04/08

#### Ethics committee reference number

IR.MUBABOL.HRI.REC.1399.104

## Health conditions studied

### 1

#### Description of health condition studied

Acute respiratory infection caused by COVID-19

#### ICD-10 code

U07.2

#### ICD-10 code description

COVID-19, virus not identified

## Primary outcomes

### 1

#### Description

O<sub>2</sub> Saturation rate (percent)

#### Timepoint

Daily

#### Method of measurement

using pulse oximeter

## Secondary outcomes

### 1

#### Description

duration of hospitalization

#### Timepoint

days of hospitalization

#### Method of measurement

counting the days from hospitalization to discharge

### 2

#### Description

duration of fever

#### Timepoint

Number of hospitalization days when the patient has a oral fever above 36.6

### Method of measurement

The patient's fever is assessed daily with an oral thermometer and the number of days that patients have a fever over 36.6 at the time of hospitalization is counted.

### 3

#### Description

duration of cough

#### Timepoint

daily

#### Method of measurement

Counting the number of days a patient coughs in hospitalized days

## Intervention groups

### 1

#### Description

Intervention group: Diet based on the principles of Persian medicine is prepared as a weekly program in three meals and given to patients. In this diet, raw materials (including saffron, sweet pomegranate juice, etc.) are added that can help treat patients with lung infections. Patients follow the same diet until discharge. Apart from this diet, no new therapeutic interventions are performed on these patients.

#### Category

Treatment - Other

### 2

#### Description

Control group: The usual diet that is provided to all patients in Iranian hospitals will be given to these patients as usual

#### Category

Other

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Damavand 3rd Shaban Hospital

##### Full name of responsible person

Seyyed Ali Mozaffarpur

##### Street address

Shahid Beheshty Av.-Parastoo St.

##### City

Damavand

##### Province

Tehran

##### Postal code

3971887511

##### Phone

+98 21 7631 9781

##### Fax

+98 21 7631 9785

### Email

seyyedali1357@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Babol University of Medical Sciences

##### Full name of responsible person

Reza Ghadimi

##### Street address

Ganjafrooz Street

##### City

Babol

##### Province

Mazandaran

##### Postal code

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##### Phone

+98 11 3219 4730

##### Email

Seyyedali1357@gmail.com

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Babol 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

Babol University of Medical Sciences

##### Full name of responsible person

Seyyedali Mozaffarpur

##### Position

Associated Professor

##### Latest degree

Ph.D.

##### Other areas of specialty/work

Traditional Medicine

##### Street address

Ganjafrooz Street

##### City

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##### Province

Mazandaran

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
Babol University of Medical Sciences  
**Full name of responsible person**  
SeyyedAli Mozaffarpur  
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Associated Professor  
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**Other areas of specialty/work**  
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## Person responsible for updating data

### Contact

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seyyed Ali Mozaffarpur  
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## Sharing plan

### Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be 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

Undecided - It is not yet known if there will be a plan to make this available

### Title and more details about the data/document

Information from the intervention will be shared after the publication of the results

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

after the publication of the results

### To whom data/document is available

people working in academic institutions

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

systematic review and meta analysis

### From where data/document is obtainable

Send email to seyyedali1357@gmail.com and submit a request

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

Send email to seyyedali1357@gmail.com and submit a request

### Comments