Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

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 • PO2 <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
O2 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.
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Sponsors / Funding sources

1

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

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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