Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effects of a diet based on Iranian medicine on clinical outcomes and laboratory biomarkers of patients with COVID-19

Protocol summary

Study aim

The effects of a diet based on Iranian medicine on clinical outcomes and laboratory biomarkers of patients with COVID-19 admitted to hospital

Design

Clinical trial with control group, with parallel intervention group, and randomized

Settings and conduct

Setting of study is Emam Reza hospital of army .In this study, 160 newly diagnosed COVID-19 hospitalized patients are selected based on inclusion and exclusion criteria . Patients are divided into two equal groups using the random function of Math lab software. Beyond standard treatment based on the protocol recommended by the Ministry of Health for hospitalized patients, intervention groups will receive a diet based on Iranian medicine and control group will receive hospital standard diet for 5 days. The course of symptoms and clinical findings will be monitored daily by the project colleagues and the paraclinical findings will be evaluated before and after the 5-day intervention.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1. Non-pregnant and non-lactating women and men over 18 years with positive PCR for Covid-19 2.Existence of at least two of the following findings: RR>20, SO2<93%, GGO>10% 3. Absence of underlying disease 4.Informed written consent to participate in the study Exclusion Criteria: 1.Participation in another clinical trial 2. when allergies or any complications happen

Intervention groups

Intervention group: receive a diet based on Iranian medicine (80 person) Control group: receive the hospital diet (low salt, low fat) (80 person) both group receive COVID-19 standard treatment (Remdesivir, prophylactic anticoagulant, and low dose corticosteroids)

Main outcome variables

need for ICU admission , duration of hospitalization, severity of shortness of breath, cough intensity, SO2 changes, RR changes, changes in inflammatory markers (ESR, CRP, LDH, WBC)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220227054140N1**
Registration date: **2022-05-25, 1401/03/04**
Registration timing: **retrospective**

Last update: **2022-05-25, 1401/03/04**
Update count: **0**

Registration date

2022-05-25, 1401/03/04

Registrant information

Name
Ramtin Hajibeygi
Name of organization / entity
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Iran (Islamic Republic of)
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+98 21 2281 7251
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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-04-21, 1401/02/01

Expected recruitment end date

2022-04-28, 1401/02/08

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
The effects of a diet based on Iranian medicine on clinical outcomes and laboratory biomarkers of patients with COVID-19

Public title
The effects of a diet based on Iranian medicine on COVID-19 patients

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Patients who have positive PCR for COVID-19 Patients with COVID-19 who have been admitted to hospital

Exclusion criteria:
Patients who are pregnant or breastfeeding Patients with underlying diseases such as: diabetes, hypertension and cancer

Age
From **18 years** old

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **160**

Randomization (investigator's opinion)
Randomized

Randomization description
Using MATLAB software version R2018b, 180 people are randomly divided into two groups of 80 intervention (A) and control (B) using randperm(n, k) command. The randperm(n, k) command randomly extracts a non-duplicate number from range 1 to n. Thus, each of the numbers 1 to 160, which represent 160 patients, can be assigned to only one of the groups A or B. There is no specific pattern for assigning to each of the groups, and only by referring to the file extracted from the program command, you can find the assignment of each number to each of groups A or B. Thus, patient number 1 is given a code 1 food package. The food package is filled based on the extracted file by a person who is not involved in the research process.

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
Research Ethics Committees of AJA University of Medical Sciences

Street address
AJA University of Medical Sciences, Shahid Etemadzadeh Street, West Fatemi Street

City
Tehran

Province
Tehran

Postal code
1411718541

Approval date
2022-02-21, 1400/12/02

Ethics committee reference number
IR.AJAUMS.REC.1400.307

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
ICU admission or intubation

Timepoint
During hospitalization, daily

Method of measurement
Evaluator report

Secondary outcomes

1

Description
Clinical symptoms (cough intensity, The degree of shortness of breath)

Timepoint
During hospitalization, daily

Method of measurement
Symptoms by asking the patient as a scale indicator and signs by monitoring the patient by the assessor

2

Description
Inflammatory markers (ESR, CRP, LDH, WBC)

Timepoint
before and after the 5 days intervention
Method of measurement
Quantitative laboratory measurements of blood samples

3

Description
Clinical examinations (RR, SO2)
Timepoint
During hospitalization, daily
Method of measurement
Through clinical examination and use of pulse oximeter

Intervention groups

1

Description
Intervention group: COVID-19 standard treatment based on the protocol recommended by the Ministry of Health for hospitalized patients (Remdesivir, prophylactic anticoagulant, and low dose corticosteroids) and a diet based on Iranian medicine (mornings: one egg and one teaspoon honey, first snack: 5 Ficus carica, lunch: a combination of 50 grams Cicer arietinum, 10 grams rice, 30 grams lamb meat, second snack: 5 Ziziphus jujuba, dinner: barley soup) for 5 days
Category
Treatment - Drugs

2

Description
Control group: COVID-19 standard treatment based on the protocol recommended by the Ministry of Health for hospitalized patients (Remdesivir, prophylactic anticoagulant, and low dose corticosteroids) and Hospital diet (low salt, low fat diet) for 5 days
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Emam Reza hospital
Full name of responsible person
Nafiseh Hosseini Yekta
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Emam Reza Hospital, Shahid Etemadzadeh Street, West Fatemi Street
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Sponsors / Funding sources

1

Sponsor
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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
Artesh 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
Artesh University of Medical Sciences
Full name of responsible person
Nafiseh Hosseini Yekta
Position
Assistant Professor
Latest degree
Specialist
Other areas of specialty/work
Traditional Medicine
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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
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be 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