

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 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

Country

Iran (Islamic Republic of)

Phone

+98 21 2281 7251

Email address

ramtin.beygi75@gmail.com

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

Street address

Emam Reza Hospital, Shahid Etemadzadeh Street,
West Fatemi Street

City

Tehran

Province

Tehran

Postal code

1411718541

Phone

+98 21 8609 6350

Email

nhyekta@yahoo.com

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Artesh University of Medical Sciences

Full name of responsible person

Saeed Soleiman Meigooni

Street address

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

City

Tehran

Province

Tehran

Postal code

1411718541

Phone

+98 21 4382 2081

Email

dr.saeed.meigooni@gmail.com

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

Street address

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

City

Tehran

Province

Tehran

Postal code

1411718541

Phone

+98 21 8609 6350

Email

nhyekta@yahoo.com

Person responsible for scientific 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

Street address

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

City

Tehran

Province

Tehran

Postal code

1411718541

Phone

+98 21 8609 6350

Email

nhyekta@yahoo.com

Person responsible for updating data**Contact****Name of organization / entity**

Artesh University of Medical Sciences

Full name of responsible person

Ramtin Hajibeygi

Position

Research assistant

Latest degree

Medical doctor

Other areas of specialty/work

General Practitioner

Street address

Unit 166, 16th floor, Razi Tower, No. 21, Saburi Ave., Pourebttehaj Street, Kashanak, Niyavaran

City

Tehran

Province

Tehran

Postal code

1978976181

Phone

+98 21 2281 7251

Fax**Email**

ramtin.beygi75@gmail.com

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