

# 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, SO<sub>2</sub><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, SO<sub>2</sub>

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

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

Artesh University of Medical Sciences

**Full name of responsible person**

Saeed Soleiman Meigooni

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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

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Artesh University of Medical Sciences

**Full name of responsible person**

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**Position**

Assistant Professor

**Latest degree**

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**Other areas of specialty/work**

Traditional Medicine

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

Artesh University of Medical Sciences

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Ramtin Hajibeygi

**Position**

Research assistant

**Latest degree**

Medical doctor

**Other areas of specialty/work**

General Practitioner

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**Fax****Email**

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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