

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

27 Jun 2026

### Investigating the effect of almond porridge, grape extract, and pea syrup on reduction of recovering period in patients with Covid-19

#### Protocol summary

##### Study aim

The effect of almond porridge, grape juice and chickpea juice on weakness and duration of hospitalization and clinical symptoms due to covid 19

##### Design

This is a single-center double-blind, placebo-controlled randomized trial with 160 (80 in each group) participants.

##### Settings and conduct

patients with Covid-19 that are hospitalized at AJA hospital will be randomized into treatment and placebo groups and will be assessed at baseline and 3-months and 6-months visits. The primary investigator of the study, who will not be involved in diagnosis and follow-up, will carry out the randomization and allocation using permuted block randomization with blocks of size 4. Treatment allocations will be concealed using opaque envelopes.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: 1) age between 18 and 65 years 2) Positive PCR test and lung involvement on CXR and positive clinical signs 3) Candidate for inpatient treatment Exclusion criteria: 1) Respiratory distress 2) Hospitalization in the intensive care unit or tracheal intubation

##### Intervention groups

Both study and control groups will receive the same food and covid-19 treatments (standard hospital regimen). During the hospital stay, in addition to the standard hospital regimen, we give the patient a mixture of almond porridge and grape juice between meals at 10 o'clock during the hospital stay. We also give chickpea juice to the patient in the 4 o'clock snack.

##### Main outcome variables

Hospital stay The Fatigue Assessment Scale (FAS) for the assessment of fatigue severity SF-36 questionnaire for the assessment of the quality of life

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20220228054150N1**

Registration date: **2022-04-08, 1401/01/19**

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

Last update: **2022-04-08, 1401/01/19**

Update count: **0**

##### Registration date

2022-04-08, 1401/01/19

##### Registrant information

##### Name

Seyed Mahdi Mirghazanfari

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 8609 6350

##### Email address

smmirghazanfari@ajaums.ac.ir

##### Recruitment status

##### Recruitment complete

##### Funding source

##### Expected recruitment start date

2022-03-20, 1400/12/29

##### Expected recruitment end date

2022-09-20, 1401/06/29

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Investigating the effect of almond porridge, grape extract, and pea syrup on reduction of recovering period in patients with Covid-19

#### Public title

Almond porridge, grape extract, and pea syrup for treatment of Covid-19

#### Purpose

Treatment

#### Inclusion/Exclusion criteria

##### Inclusion criteria:

Age between 18 and 65 years Conscious consent to participate in the study positive PCR test and lung involvement on CT scan and positive clinical signs including fever greater than 38 degrees or hot flashes with at least one of the symptoms of dry cough, 24 Respiratory rate per minute, headache or body aches, weakness and lethargy, anosmia (olfactory disorder) or taste disturbances and anorexia Absence of respiratory distress Candidates for hospitalization

##### Exclusion criteria:

admission to the intensive care unit patients with intubation

#### Age

From **18 years** old to **65 years** old

#### Gender

Both

#### Phase

3

#### Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

#### Sample size

Target sample size: **160**

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

Patients will be equally randomized into treatment or control groups in a 1:1 ratio. A specific random code will be assigned to each patient using the Microsoft Office Excel software. The primary investigator of the study, who will not be involved in diagnosis and follow-up, will carry out the randomization and allocation using permuted block randomization with blocks of size 4. Treatment allocations will be concealed using opaque envelopes.

#### Blinding (investigator's opinion)

Double blinded

#### Blinding description

The allocations will be kept in confidential and opaque envelopes and will be exposed at the end of the trial. Placebo will be completely indistinguishable from treatment. Randomizations, drug administration, rating, data entry, and statistical analyses will be conducted by separate individuals that are blinded to drug allocations.

#### Placebo

Used

#### Assignment

Parallel

#### Other design features

#### Secondary Ids

empty

#### Ethics committees

##### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of AJA University of Medical Sciences

##### Street address

AJA university of medical sciences, Etemadzadeh st, West Fatemi st,

##### City

Tehran

##### Province

Tehran

##### Postal code

1411718541

#### Approval date

2022-03-12, 1400/12/21

#### Ethics committee reference number

IR.AJAUMS.REC.1400.322

#### Health conditions studied

##### 1

#### Description of health condition studied

COVID-19

#### ICD-10 code

U07.1

#### ICD-10 code description

COVID-19, virus identified

#### Primary outcomes

##### 1

#### Description

The Fatigue Assessment Scale (FAS) score

#### Timepoint

0, 3, 6 months after treatment

#### Method of measurement

The Fatigue Assessment Scale (FAS)

##### 2

#### Description

hospital stay

#### Timepoint

after the initiation of treatment till discharge from hospital

#### Method of measurement

health records

## Secondary outcomes

1

### Description

ESR, CRP

### Timepoint

during admission

### Method of measurement

laboratory measurement using electroimmunoassay (EIA)

## Intervention groups

1

### Description

Intervention group: A mixture of almond porridge and grape juice (containing 25 grams of almonds and 8 cc of grape juice) is given to the patient in a disposable container in the snack at 10 o'clock and given to the patient during the hospital stay. Also in the snack at 16 o'clock, chickpeas (containing 30 grams of chickpeas) will be given in a disposable container during the hospital stay.

### Category

Treatment - Drugs

2

### Description

The placebo will be similar to the intervention in terms of shape, taste, color and smell and will be given to the patient at 10 and 16 o'clock.

### Category

Placebo

## Recruitment centers

1

### Recruitment center

#### Name of recruitment center

AJA university of medical sciences hospital

#### Full name of responsible person

Seyed Mehdi Mirghazanfari

#### Street address

AJA university of medical sciences, Etemadzadeh st,  
West Fatemi st,

#### City

Tehran

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#### Postal code

1411718541

#### Phone

+98 21 8833 7922

#### Email

smmirghazanfari@ajaums.ac.ir

## Sponsors / Funding sources

1

### Sponsor

#### Name of organization / entity

Artesh University of Medical Sciences

#### Full name of responsible person

Seyed Mehdi Mirghazanfari

#### Street address

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West Fatemi st,

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#### Email

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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

Seyed Mahdi Mirghazanfari

#### Position

Associate professor

#### Latest degree

Ph.D.

#### Other areas of specialty/work

Nutrition

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west Fatemi St, Tehran

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Artesh University of Medical Sciences

**Full name of responsible person**

Seyed Mahdi Mirghazanfari

**Position**

Associate professor

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Artesh University of Medical Sciences

**Full name of responsible person**

Seyed Mahdi Mirghazanfari

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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