

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

27 May 2026

### Investigating the effect of sweet almond ,Oral product, as a supplement in patients with COVID 19

#### Protocol summary

##### Study aim

Evaluation of the effectiveness of sweet almond, oral product in improving Respiratory symptoms of patients with Quaid 19

##### Design

This study is a Controlled Clinical Trial that is performed on 60 patients with COVID19, with respiratory symptoms. Patients were divided into two random groups using a table of random numbers and and a code assigned to them. The intervention group receive sweet almond oral product and the prescribed drugs according to protocol and for the control group, given only prescription drugs according to protocol.

##### Settings and conduct

Patients who have been hospitalized with coronavirus diagnosis, at Masih Daneshvari Hospital in Tehran and have any respiratory symptoms receive 10 cc of oral almonds sweet product after each meal for 6 days. by. The severity of dyspnea, cough and sleep quality, is evaluated with, questionnaire Dyspnoea, Leicester Cough questionnaire and The Petersburg Questionnaire and recorded.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: All patients with corona (confirmed by test or CT) two years and older of both sexes who have one of the clinical manifestations (shortness of breath and cough). Exclusion criteria: Any allergies to Almonds sweet or other foods Diabetic patients Taking Hospitalization in the intensive care unit

##### Intervention groups

Patients with COVID19, who have any respiratory symptoms, receive oral product of sweet almond and prescription drugs, and the control group is given only prescription drugs.

##### Main outcome variables

almond sweet shortness of breath cough Intensity

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20180712040446N2**

Registration date: **2020-07-01, 1399/04/11**

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

Last update: **2020-07-01, 1399/04/11**

Update count: **0**

##### Registration date

2020-07-01, 1399/04/11

##### Registrant information

##### Name

Atefe Sharif

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 2247 3630

##### Email address

atf.sharif@sbmu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-06-30, 1399/04/10

##### Expected recruitment end date

2020-08-31, 1399/06/10

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Investigating the effect of sweet almond ,Oral product, as a supplement in patients with COVID 19

## Public title

Investigating the effect of sweet almond on symptoms of COVID 19

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

All patients with corona (confirmed by test or CT) who have one of the clinical manifestations (shortness of breath and cough). Patients hospitalized

### Exclusion criteria:

Any allergies to Almonds sweet or other foods Patients who ate Almonds sweet regularly Inability to take medication orally Diabetic patients Taking Opioid medications Use of Antitussive products Suffering from other respiratory diseases Hospitalization in the intensive care unit

## Age

From 2 years old

## Gender

Both

## Phase

3

## Groups that have been masked

No information

## Sample size

Target sample size: 60

## Randomization (investigator's opinion)

Randomized

## Randomization description

Random number table: Patients using random number tables and assigned according to code given to them, they are divided into two random groups.

## 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 Shahid Beheshti University of Medical Sciences(SBUMS)

##### Street address

Shahid Beheshti University of Medical Sciences, Arabi Ave, Daneshjoo Blvd, Velenjak, Tehran, Iran.

##### City

Tehran

## Province

Tehran

## Postal code

19839-63113

## Approval date

2020-04-08, 1399/01/20

## Ethics committee reference number

IR.SBMU.NRITLD.REC.1399.120

## Health conditions studied

### 1

#### Description of health condition studied

COVID-19

#### ICD-10 code

U07.1

#### ICD-10 code description

COVID-19

### 2

#### Description of health condition studied

Cough

#### ICD-10 code

R05

#### ICD-10 code description

Cough

### 3

#### Description of health condition studied

Shortness of breath

#### ICD-10 code

R06.02

#### ICD-10 code description

Shortness of breath

### 4

#### Description of health condition studied

Fever

#### ICD-10 code

R50.9

#### ICD-10 code description

Fever, unspecified

## Primary outcomes

### 1

#### Description

Severity shortness of breath

#### Timepoint

At the beginning of the study, 3 and 6 days after the start using product

#### Method of measurement

Dyspnoea-12 questionnaire

### 2

#### Description

Severity of cough  
**Timepoint**  
At the beginning of the study, 3 and 6 days after the start using product  
**Method of measurement**  
Leicester Cough Questionnaire

## Secondary outcomes

### 1

**Description**  
Sleep Quality  
**Timepoint**  
At the beginning of the study, 3 and 6 days after the start of product consumption  
**Method of measurement**  
Petersburg Sleep Quality Questionnaire

## Intervention groups

### 1

**Description**  
Intervention group: Sweet almond product, 10 cc, three times a day, for 6 days, after each meal  
**Category**  
Treatment - Drugs

### 2

**Description**  
Control group: Standard treatment for COVID-19, according to the protocol of the Ministry of Health, including hydroxychloroquine sulfate (Amin Isfahan Pharmaceutical Company) in a dose of 200 mg, twice a day for 14 days  
**Category**  
Treatment - Drugs

## Recruitment centers

### 1

**Recruitment center**  
**Name of recruitment center**  
Masih Daneshvari hospital  
**Full name of responsible person**  
Ali Abdolahinia  
**Street address**  
Shahid Bahonar St., Darabad  
**City**  
Tehran  
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Tehran  
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1956944413  
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+98 21 2712 3000  
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+98 21 2610 9484  
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pr.nritld@sbmu.ac.ir  
**Web page address**  
<http://nritld.sbmu.ac.ir>

## Sponsors / Funding sources

### 1

**Sponsor**  
**Name of organization / entity**  
Shahid Beheshti University of Medical Sciences  
**Full name of responsible person**  
Afshin Rezqi  
**Street address**  
7th Floor, Bldg No.2, Shahid Beheshti Medical University, Arabi Ave, Daneshjoo Blvd, Velenjak, Tehran, Iran  
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**Fax**  
+98 21 2243 3455  
**Email**  
[Intl\\_office@sbmu.ac.ir](mailto:Intl_office@sbmu.ac.ir)  
**Web page address**  
<http://en.sbmu.ac.ir>

**Grant name**  
**Grant code / Reference number**  
**Is the source of funding the same sponsor organization/entity?**  
Yes  
**Title of funding source**  
Shahid Beheshti 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**  
Shahid Beheshti University of Medical Sciences  
**Full name of responsible person**  
Ali Abdolahinia  
**Position**  
Assistant Professor  
**Latest degree**  
Ph.D.  
**Other areas of specialty/work**

Traditional Medicine

**Street address**

Masih Daneshvari Hospital, Darabad Avenue, Shahid Bahonar roundabout, Tehran, Iran

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**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Mohammad Kamalinejad

**Position**

Medicinal Plant Researcher

**Latest degree**

Master

**Other areas of specialty/work**

Medicinal Plants

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Iran, Tehran, Valiasr St , Before Niayesh Highway, School Of Pharmacy, Shahid Beheshti Medical University

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**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Atefe Sharif

**Position**

Iranian medicine specialist

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Traditional Medicine

**Street address**

No.8 ,School Of Traditional medicine, Shahid Beheshti Medical University, Shams, Opposite Tavanir Alley - Valiasr St., Tehran

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**Province**

Tehran

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1516745811

**Phone**

+98 21 8877 3521

**Email**

atf.sharif@sbmu.ac.ir

**Sharing plan**

**Deidentified Individual Participant Data Set (IPD)**

Yes - There is 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**

Yes - There is a plan to make this available

**Data Dictionary**

Yes - There is a plan to make this available

**Title and more details about the data/document**

A part of the data, such as information about the main consequence, will be shared.

**When the data will become available and for how long**

Start the access period 6 months after publishing the results

**To whom data/document is available**

Every one

**Under which criteria data/document could be used**

Using in research and treatment projects

**From where data/document is obtainable**

Ali Abdolahinia : aaliabd@yahoo.com , Masih Daneshvari Hospital, Darabad Avenue, Shahid Bahonar roundabout, Tehran, Iran

**What processes are involved for a request to access data/document**

For 10 days, after sending the request via email, it will be sent to them.

**Comments**