

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

31 May 2026

### Evaluating the Effects of CoQ10, melatonin, vitamin B groups, vitamin D, and probiotic on reducing COVID-19 symptoms during recovery- A randomized double blind controlled Clinical Trial

#### Protocol summary

##### Study aim

Evaluating the Effects of CoQ10, melatonin, vitamin B groups, vitamin D, and probiotic on reducing COVID-19 symptoms during recovery

##### Design

80 participants (no=40 per group) are randomly assigned to intervention and placebo group using random digit table

##### Settings and conduct

This double blinded study will be performed in private clinic. At base line and after 30 days of intervention with supplement/placebo, Fatigue Severity Scale (FSS) for fatigue, Pittsburgh Sleep Quality Index (PSQI) for sleep, Hospital Anxiety and Depression Scale (HADS) for anxiety, Patient Assessment of Constipation-Symptoms (PAC-SYM) for constipation will be completed. Severity (using visual analog scale-VAS), duration, and frequency of headache will be recorded.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: diagnosed with COVID-19 according to WHO criteria; willing to participate in the study; age 18 years and older. Exclusion criteria: discharged with positive PCR test for COVID-19; pregnancy; lactation; vitamin D deficiency based on lab test (<30 ng/ml); enteral or parental nutrition requirement after discharge.

##### Intervention groups

Patients will receive CoQ10, melatonin, vitamin B groups, vitamin D and probiotic 1000 mg capsule (Viralian Group company) or placebo BD for 30 days. Placebo contains maltodextrine.

##### Main outcome variables

Score of Fatigue Severity Scale (FSS) for fatigue; Pittsburgh Sleep Quality Index (PSQI) for sleep; Hospital Anxiety and Depression Scale (HADS) for anxiety; Patient Assessment of Constipation-Symptoms (PAC-SYM) for constipation Severity (using visual analog scale-VAS); duration, and frequency of headache

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20140804018677N21**

Registration date: **2022-06-26, 1401/04/05**

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

Last update: **2022-06-26, 1401/04/05**

Update count: **0**

##### Registration date

2022-06-26, 1401/04/05

##### Registrant information

##### Name

soodeh razeghi Jahromi

##### Name of organization / entity

Tehran University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 6634 8500

##### Email address

razeghi@sina.tums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2022-05-05, 1401/02/15

##### Expected recruitment end date

2022-10-07, 1401/07/15

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

### Scientific title

Evaluating the Effects of CoQ10, melatonin, vitamin B groups, vitamin D. and probiotic on reducing COVID-19 symptoms during recovery- A randomized double blind controlled Clinical Trial

### Public title

Effects of CoQ10, melatonin, vitamin B groups, vitamin D. and probiotic on reducing COVID-19 symptoms during recovery

### Purpose

Treatment

### Inclusion/Exclusion criteria

#### Inclusion criteria:

Diagnosed with COVID-19 according to WHO criteria  
Willing to participate in the study Age 18 years and older

#### Exclusion criteria:

Discharged with positive PCR test for COVID-19  
Pregnancy Lactation Vitamin D deficiency based on lab test (<30 ng/ml) Enteral or parental nutrition requirement after discharge

### Age

From **18 years** old

### Gender

Both

### Phase

3

### Groups that have been masked

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

### Sample size

Target sample size: **80**

### Randomization (investigator's opinion)

Randomized

### Randomization description

Participants will have equal chance to be assigned to studied groups. We will use random digits table to make random sequence. After determining the first number, we will continue downward and allocate even numbers to cases and odd numbers to placebo. As in small sample sizes, it would be probable that one group be completed earlier, if one group completed earlier, we will allocate the other assigned numbers to other group. A person out of study group will put her figure on one digit of the table with closed eyes and according to assumed agreement will go downward through the table and write the numbers down until completing the sample size in each group. Code "A" will allocated to even numbers and considered as "intervention group" and code "B" will allocated to odd numbers and considered as "placebo group". At the end we will have the sequence of 80 specific numbers and A&B codes. A person out of study team will put the numbers in sealed packets till the time of sampling

### Blinding (investigator's opinion)

Double blinded

### Blinding description

It is a double blind study. A third person out of study team have the sequence of codes that provide the team with sealed pockets containing allocation code (supplement and placebo) at the time of sampling. The following groups of people: participants, research team including principle investigator, data collectors, and outcome assessors will be blind

### Placebo

Used

### Assignment

Parallel

### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Research Ethics committees of vice-cancellor in  
Research Affairs-Shahid Beheshti University of Medica

##### Street address

7th Floor, Bldg No.2, Shahid Beheshti University of  
Medical Sciences, Arabi Ave, Daneshjoo Blvd,  
Velenjak

##### City

Tehran

##### Province

Tehran

##### Postal code

19839-63113

#### Approval date

2022-02-27, 1400/12/08

#### Ethics committee reference number

IR.SBMU.RETECH.REC.1400.1079

## 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

Fatigue Severity

#### Timepoint

Baseline and at the end of the study

#### Method of measurement

Fatigue Severity Scale (FSS)

## 2

### **Description**

Sleep Quality

### **Timepoint**

Baseline and at the end of the study

### **Method of measurement**

Pittsburgh Sleep Quality Index (PSQI)

## 3

### **Description**

Anxiety

### **Timepoint**

Baseline and at the end of the study

### **Method of measurement**

Hospital Anxiety and Depression Scale (HADS)

## 4

### **Description**

Constipation

### **Timepoint**

Baseline and at the end of the study

### **Method of measurement**

Patient Assessment of Constipation-Symptoms (PAC-SYM)

## 5

### **Description**

Headache severity

### **Timepoint**

Baseline and at the end of the study

### **Method of measurement**

Visual analog scale-VAS

## 6

### **Description**

Headache duration

### **Timepoint**

Baseline and at the end of the study

### **Method of measurement**

Headache diary

## 7

### **Description**

Headache Frequency

### **Timepoint**

Baseline and at the end of the study

### **Method of measurement**

Headache diary

## **Secondary outcomes**

empty

## **Intervention groups**

### 1

#### **Description**

Intervention group: 1000 mg capsul of CoQ10, melatonin, vitamin B groups, vitamin D. and probiotic capsule (Viralian Group company) BD for 30 days

#### **Category**

Treatment - Other

### 2

#### **Description**

Control group: 1000 mg capsul of placebo (Viralian Group company) BD for 30 days

#### **Category**

Placebo

## **Recruitment centers**

### 1

#### **Recruitment center**

##### **Name of recruitment center**

Private Clinic

##### **Full name of responsible person**

Soodeh Razeghi Jahromi

##### **Street address**

5th floor, Pezeshkan-e-Iran-e-Ma building, 24th Alley, Ghaem Magham Farahani St.

##### **City**

Tehran

##### **Province**

Tehran

##### **Postal code**

1586984447

##### **Phone**

+98 21 8832 8351

##### **Email**

soodehrazeghi@gmail.com

## **Sponsors / Funding sources**

### 1

#### **Sponsor**

##### **Name of organization / entity**

Shahid Beheshti University of Medical Sciences

##### **Full name of responsible person**

Afshin Zarghi

##### **Street address**

7th Floor, Bldg No.2, Shahid Beheshti University of Medical Sciences, Arabi Ave, Daneshjoo Blvd, Velenjak

##### **City**

Tehran

##### **Province**

Tehran

##### **Postal code**

1981619573

##### **Phone**

+98 21 2235 7483

##### **Email**

azarghi@yahoo.com

#### **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**

Nutrition and food science faculty, Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Soodeh Razghei Jahromi

**Position**

Associate professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Nutrition

**Street address**

No. 7, West Arghavan St., Farahzadi Blv., Qods Town

**City**

Tehran

**Province**

Tehran

**Postal code**

193954741

**Phone**

+98 21 2235 7483

**Email**

soodehrazeghi@gmail.com

**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Nutrition and food science faculty, Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Soodeh Razghei Jahromi

**Position**

Associate professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Nutrition

**Street address**

No. 7, West Arghavan St., Farahzadi Blv., Qods Town

**City**

Tehran

**Province**

Tehran

**Postal code**

193954741

**Phone**

+98 21 2235 7483

**Email**

soodehrazeghi@gmail.com

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

Nutrition and food science faculty, Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Soodeh Razghei Jahromi

**Position**

Associate professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Nutrition

**Street address**

No. 7, West Arghavan St., Farahzadi Blv., Qods Town

**City**

Tehran

**Province**

Tehran

**Postal code**

193954741

**Phone**

+98 21 2235 7483

**Email**

soodehrazeghi@gmail.com

**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**

All data would be available to public

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

starting 6 months after publication

**To whom data/document is available**

To all

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

No other criteria

**From where data/document is obtainable**

Email to soodehrazeghi@gmail.com

**What processes are involved for a request to access**

**data/document**

sending email to me

**Comments**