Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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
Evaluateing 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
Ṡcore 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

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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 comittees 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

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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.
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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
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1981619573
Phone
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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
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Person responsible for updating data

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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 critaria

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