Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Inflammation control in patients with COVID-19 using melatonin supplement compare to controls referred to Imam Khomani Hospital

Protocol summary

Study aim
The relation between melatonin and inflammation control in patients with COVID-19

Design
Forty patients enter the intervention and control groups randomly and in parallel by the physician, and the researcher and data analyzer are blind.

Settings and conduct
This study is performed on patients referred to Imam Khomeini Hospital in Tehran.

Participants/Inclusion and exclusion criteria
Patients enter the study with mild to moderate COVID-19 who receive Hydroxy chloroquine and have CTscan and clinical symptoms and are confirmed by physician. Patients with certain underlying diseases as well as pregnant and breastfeeding mothers are not included in the study.

Intervention groups
One group of patients receive melatonin and the control group does not.

Main outcome variables
Outcome of the disease is measured after two weeks in terms of clinical symptoms and CRP factor.

General information

Reason for update

Acronym
CEM

IRCT registration information
IRCT registration number: **IRCT20200922048804N1**
Registration date: **2020-10-06, 1399/07/15**
Registration timing: **retrospective**

Last update: **2020-10-06, 1399/07/15**
Update count: **0**

Registration date
2020-10-06, 1399/07/15

Registrant information

Name
Zahra Alizadeh

Name of organization / entity
Immunology, Asthma & Allergy Research Institue

Country
Iran (Islamic Republic of)

Phone
+98 21 6693 5855

Email address
z-alizadehs@farabi.tums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-08-05, 1399/05/15

Expected recruitment end date
2020-10-01, 1399/07/10

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Inflammation control in patients with COVID-19 using melatonin supplement compare to controls referred to Imam Khomani Hospital

Public title
Melatonin in COVID-19

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
mild to moderate patients with COVID-19 who receive Hydroxy chloroquine Confirmation of the disease is based on CT scan and clinical symptoms and physician diagnosis Patients 25-65 years

Exclusion criteria:
Patient with depression, COPD, sleep apnea and seizure Patients with severe kidney problem (eGFR<30 ml/min) Patients with severe liver problem Patients who receive fluvoxamine, benzodiazepine or zolpidem patients who receive drugs that extends QT Pregnant and breastfeeding mothers Patients who have allergy to melatonin

Age
From **25 years** old to **65 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Investigator
- Data analyser

Sample size
Target sample size: **20**

Randomization (investigator's opinion)
Not randomized

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description
In this project, the participant is explained about participating in the project and informed consent is obtained. Also, the physician who is in contact with the patient is aware of the intervention groups and is responsible for following up on the participants.Researcher and data analyst are blind

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Tehran University of Medical Sciences

Street address
Enghelab st.

City
Tehran

Province
Tehran

Postal code
1417613151

Approval date
2020-03-29, 1399/01/10

Ethics committee reference number
IR.TUMS.VCR.REC.1399.068

Health conditions studied

1

Description of health condition studied
COVID-19

ICD-10 code
U07.2

ICD-10 code description
Clinically-epidemiologically diagnosed COVID-19

Primary outcomes

1

Description
headache

Timepoint
10-14 days

Method of measurement
COVID-19 questionnaire

2

Description
lung infection

Timepoint
10-14 days

Method of measurement
CTscan and physician diagnosis

3

Description
CRP (C reactive protein)

Timepoint
10-14 days

Method of measurement
Lab test

4

Description
fever

Timepoint
10-14days

Method of measurement
questionnaire

5

Description
vomiting

Timepoint
10-14 days

Method of measurement
Questionnaire

6

Description
no smelling
Timepoint
10-14 days
Method of measurement
questionnaire

7

Description
no taste
Timepoint
10-14 days
Method of measurement
questionnaire

8

Description
cough
Timepoint
10-14 days
Method of measurement
Questionnaire

9

Description
Respiratory distress
Timepoint
10-14days
Method of measurement
questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Prescribing 6 mg of melatonin capsules made by Elite factory for 2 weeks, which should be consumed half an hour before bedtime every night in low light conditions and even sleep in light conditions. These explanations were described to each patient. Melatonin is a hormonal supplement used to regulate sleep. Patients (if needed) receive medication prescribed by the doctor (hydroxychloroquine, acetaminophen, naproxen).
Category
N/A

2

Description
Control group: Patients (if needed) receive medication prescribed by the doctor (hydroxychloroquine, acetaminophen, naproxen).
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Khomeini Hospital
Full name of responsible person
Nastaran Keyhanian
Street address
Keshavarz Blvd
City
Tehran
Province
Tehran
Postal code
۱۴۱۹۷۳۳۱۴۱
Phone
+98 21 6693 5855
Email
nkeyhanian1366@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Dr. Mohammad Ali Sahraian
Street address
Enghelab st.
City
Tehran
Province
Tehran
Postal code
1417613151
Phone
+98 21 6405 3334
Email
okazi@tums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tehran 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
Immunology, Asthma & Allergy Research Institute
Full name of responsible person
Zahra Alizadeh
Position
Resaercher
Latest degree
Ph.D.
Other areas of specialty/work
Biomedicine
Street address
Dr. Gharib St.
City
Tehran
Province
Tehran
Postal code
1419733151
Phone
+98 21 6693 5855
Email
zalizade@yahoo.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Immunology, Asthma & Allergy Research Institute
Full name of responsible person
Zahra Alizadeh
Position
Researcher
Latest degree
Ph.D.
Other areas of specialty/work
Biomedicine
Street address
Dr. Gharib st.
City
Tehran
Province
Tehran
Postal code
1419733151
Phone
+98 21 6693 5855
Email
zalizade@yahoo.com

Person responsible for updating data

Contact
Name of organization / entity
Immunology, Asthma & Allergy Research Institute
Full name of responsible person
Zahra Alizadeh
Position
Researcher
Latest degree
Ph.D.
Other areas of specialty/work
Biomedicine
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Dr. Gharib
City
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Email
zalizade@yahoo.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
Not applicable
Data Dictionary
Not applicable
Title and more details about the data/document
Information about the main outcome can be shared.
When the data will become available and for how long
Access will start after printing the results.
To whom data/document is available
The data will be available to researchers working in academic and scientific institutions.
Under which criteria data/document could be used
Data access is possible upon formal request.
From where data/document is obtainable
Zahra Alizadeh zalizade@yahoo.com
What processes are involved for a request to access data/document
Send a formal request by email.
Comments