Clinical Trial Protocol
Iranian Registry of Clinical Trials

30 May 2026

Evaluation of the efficacy of melatonin tablets as auxiliary medication in accelerating the improvement of the COVID-19 symptoms and clinical findings: A double-blind randomized and placebo controlled trial

Protocol summary

Study aim

Comparing the effects of melatonin and placebo tablets on the: 1- recovery duration of clinical symptoms (fever, cough and myalgia) 2-improvement time of the laboratory parameters 3-duration of radiology-symptoms remission

Design

The confirmed and suspicious COVID-19 patients who have been admitted to Bohlool Hospital and meet the study criteria are randomly assigned to the two groups of intervention and control. At the group allocation stage, the groups are homogenized in terms of age, gender and illness. Also, the number of confirmed and suspicious patients will be equal in the two groups. Then, for preventing medication interference all the prescriptions are assessed by two specialist doctors.

Settings and conduct

The research will be conducted at Bohlool Hospital. At admission, all patients are given 200 mg of hydroxychloroquine every 12 hours as the main treatment of COVID-19. Then, the pharmacist will give the two weeks supply of melatonin and placebo tablets to the researcher in numbered packages, neither of them knows the content. In the medication group, 3 mg melatonin tablets are given three times a day for 2 weeks. In the placebo group, vitamin B containing tablets with the same appearance are given with the same method and duration as the main medicine.

Participants/Inclusion and exclusion criteria

The consent to participate The confirmed and suspicious COVID-19 patients Not participating in other clinical trials simultaneously

Intervention groups

Initially, all patients are treated according to the standard treatment of Ministry of Health (Hydroxychloroquine 200 tablets every 12 hours for 14-17 days). Then, the patients are divided into two groups: one group is given the melatonin tablet as an intervention group, the other group will receive a placebo tablet containing vitamin B.

Main outcome variables

COVID-19

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200408046988N1**
Registration date: **2020-04-29, 1399/02/10**
Registration timing: **registered_while_recruiting**

Last update: **2020-04-29, 1399/02/10**
Update count: **0**

Registration date

2020-04-29, 1399/02/10

Registrant information

Name

Najmeh Davoudian

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 5723 6833

Email address

najmeh.davoudian@gmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-04-14, 1399/01/26

Expected recruitment end date

2020-06-15, 1399/03/26

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluation of the efficacy of melatonin tablets as auxiliary medication in accelerating the improvement of the COVID-19 symptoms and clinical findings: A double-blind randomized and placebo controlled trial

Public title
Evaluation of the efficacy of melatonin tablets as auxiliary medication in accelerating the improvement of the COVID-19 symptoms and clinical findings
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Consent to participate in the study Confirmed and suspicious COVID-19 patients Not participating in another clinical trial plan simultaneously
Exclusion criteria:
Lack of consent for the study Changing the other routine medications during the project
Age
No age limit
Gender
Both

Phase
2-3
Groups that have been masked
No information
Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
Balanced block randomization
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
"Ethics in Research Committee" of Gonabad University of Medical Sciences
Street address
Gonabad University of medical sciences, Asia Ave., Gonabad, Khorasan- e Razavi
City
Gonabad
Province
Razavi Khorasan
Postal code
9691793718
Approval date
2020-04-13, 1399/01/25
Ethics committee reference number
IR.GMU.REC.1399.016

Health conditions studied

1

Description of health condition studied
COVID-19
ICD-10 code
U07.01
ICD-10 code description
COVID-19

Primary outcomes

1

Description
Confirmed and possible Coronavirus 2019
Timepoint
at the time of admission
Method of measurement
CT scan - PCR test Corona virus

Secondary outcomes

1

Description
laboratory study
Timepoint
daily
Method of measurement
CBC diff-ABG

Intervention groups

1

Description
Intervention group: Melatonin 3 mg tablets will be given every eight hours for all patients undergoing standard treatment for Qovid 19 (Hydroxychloroquine 200 tablets every 12 hours)
Category
Treatment - Drugs

2

Description
Control group: All patients will be given the standard treatment for Qovid 19 (Hydroxychloroquine 200 tablets every 12 hours). Then placebo tablets with the same shape as the melatonin tablets will be prescribed every 8 hours.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Bohlool hospital
Full name of responsible person
Najmeh Davoodian
Street address
Saadi St., Vahdat Blvd, Gonabad, Khorasan Razavi,
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Gonabad University of Medical Sciences
Full name of responsible person
Shayla khosravan
Street address
Research and Technology Deputy of Gonabad University of Medical Sciences, Asian Road, Gonabad, Khorasan-E Razavi
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khosravan@gmu.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Gonabad 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
Gonabad University of Medical Sciences
Full name of responsible person
Najmeh Davoodian
Position
Associated professor
Latest degree
Specialist
Other areas of specialty/work
Internal Medicine
Street address
Deputy of Educational and Research, Clinical Research Development Unit, , Behlool Hospital, Saadi St., Vahdat Blvd., Gonabad, Khorasan-e Razavi
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Person responsible for scientific inquiries

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Person responsible for updating data

Contact

Name of organization / entity

Gonabad University of Medical Sciences

Full name of responsible person

Najmeh Davoodian

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

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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 the potential collected data will be publishable after making the participants unidentifiable.

When the data will become available and for how long

Due to the importance of studies on COVID-19 immediately after the completion of the study

To whom data/document is available

available for people working in academic institutions or people working in businesses can also apply to receive it

Under which criteria data/document could be used

All analyzes should be performed after coordination with the corresponding author of the project.

From where data/document is obtainable

For information, please refer to the corresponding author of the project, Dr. Najmeh Davoodian najmeh.davoudian@gmail.com Deputy of Education and Research, Clinical Research Development Unit, , Behlool Hospital, Saadi St., Vahdat Blvd., Gonabad, Khorasan-e Razavi

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

After receiving the request, based on the importance of the plan, it will be answered within 24-48 hours

Comments