

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 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

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Razavi Khorasan

Postal code

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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

Bohloul hospital

Full name of responsible person

Najmeh Davoodian

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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

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Research and Technology Deputy of Gonabad
University of Medical Sciences, Asian Road, Gonabad,
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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, , Behloul Hospital, Saadi
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Person responsible for scientific inquiries

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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, , Behloul 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