

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Jun 2026

Evaluating the effect of Melatonin in prognosis and clinical improvement in patients with COVID-19: A Randomized Clinical Trial

Protocol summary

Study aim

Determining the effect of melatonin on clinical improvement and prognosis of patients with Covid-19

Design

The randomized double-blind clinical trial, with parallel design in phase 3, conducted on 60 patients

Settings and conduct

This study is a randomized, double-blind clinical trial that will be performed on adult patients (aged 18 to 75 years) with a definitive diagnosis of COVID-19 referred to the specialized clinic of Shahid Beheshti Hospital. In this study, 60 patients who according to the guidelines of the World Health Organization (WHO) and the latest flowchart of diagnosis and treatment of Covid 19 disease in the outpatient and inpatient services of the Ministry of Health and Medical Education (March 4, 2020) diagnosed as a definitive COVID-19 and according to the physician and the clinical signs and symptoms of mild to moderate disease without pulmonary involvement and no signs of respiratory distress in them will be included in the study. The therapist and the patient are unaware of the allocation of the treatment regimen and the study is double-blind

Participants/Inclusion and exclusion criteria

Patients aged 18 to 75 years with a definitive diagnosis of Covid-19 who are hospitalized in the ward are included in the study. Patients with intolerance to melatonin or taking immunosuppressive drugs in the last three months have been excluded from the study .

Intervention groups

The intervention group will receive melatonin supplement at a dose of 18 mg twice a day for 7 days and orally with standard treatment. And the control group will receive standard treatment.

Main outcome variables

The need for oxygen therapy, death rate, side effects, the amount of hospitalization in the intensive care unit for 28 days and, if necessary, the number of days of hospitalization in the intensive care unit in two

investigated groups.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200426047206N4**

Registration date: **2020-11-01, 1399/08/11**

Registration timing: **registered_while_recruiting**

Last update: **2020-11-01, 1399/08/11**

Update count: **0**

Registration date

2020-11-01, 1399/08/11

Registrant information

Name

Salman Khazaei

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 81 3838 0548

Email address

salman.khazaei61@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-10-22, 1399/08/01

Expected recruitment end date

2020-12-21, 1399/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluating the effect of Melatonin in prognosis and clinical improvement in patients with COVID-19: A Randomized Clinical Trial

Public title

Effect of Melatonin in treatment of COVID-19

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age between 18-75 year Hospitalized in ward Confirmed diagnosis with PCR Elapsed less than 48 hour from symptom onset Not pregnant or breastfeeding Do not have moderate to severe liver and renal problems. Not treated with immunosuppressive drugs during the last 3 months

Exclusion criteria:

Drug intolerance

Age

From **18 years** old to **75 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

For randomization, we will use the method of Balanced Block Randomization (block size: 4). For this purpose, we prepare four sheets of paper. On the two sheets, we write the I meaning "Intervention" and on the other two sheets we write the P meaning "Placebo". Mix the sheets together and place them in the desk drawer. When referring to any of the eligible patients, one of the sheets was randomly taken out, and based on this sheet, I or P was assigned to one of the two groups of intervention (melatonin recipient) or comparison (placebo recipient). They will be. Extracted tabs will not be returned to the drawer until all four tabs have been extracted. After randomly pulling out all four sheets, all the sheets are returned to the drawer and the above procedure will be continued for the next four patients until the desired sample size (60 patients) is reached.

Blinding (investigator's opinion)

Double blinded

Blinding description

Both the intervention and control groups will receive drugs with the same appearance, the intervention group will receive melatonin in addition to the standard drugs, and the control group will receive standard drugs and placebo. The drugs for each group are specified with a special code and the patient and the treating physician will be unaware of the type of drug used by the patients.

Therefore, the study will be conducted in a double-blind manner.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Hamadan University of Medical Sciences

Street address

Fahmideh Street

City

Hamadan

Province

Hamadan

Postal code

6517838778

Approval date

2019-10-19, 1398/07/27

Ethics committee reference number

IR.UMSHA.REC.1399.592

Health conditions studied

1

Description of health condition studied

Covid-19

ICD-10 code

U07.1

ICD-10 code description

covid-19

Primary outcomes

1

Description

The amount of hospitalization in the intensive care unit during 28 days

Timepoint

Day 28 after treatment

Method of measurement

view patients medical file

2

Description

Need to oxygen therapy rate

Timepoint

During treatment

Method of measurement

view patients medical file

3**Description**

Rate of sleep and depression

Timepoint

Hospital Anxiety and Depression Questionnaire

Method of measurement

Score

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: Melatonin supplement at a dose of 18 mg twice a day for 7 days and orally, with standard treatment

Category

Treatment - Drugs

2**Description**

Control group: They will receive the national standard treatment of Covid-19.

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Shahid Beheshti Hospital

Full name of responsible person

Dr Saman Talebi

Street address

Eram Street

City

Hamadan

Province

Hamadan

Postal code

6516848741

Phone

+98 81 3827 4184

Email

salman.khazaei61@gmail.com

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Hamedan University of Medical Sciences

Full name of responsible person

Saeed Bashirian

Street address

Fahmideh Street

City

Hamadan

Province

Hamadan

Postal code

6571838678

Phone

+98 81 3838 0717

Email

s_bashirian@yahoo.com

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

No

Title of funding source

Hamadan 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**

Hamedan University of Medical Sciences

Full name of responsible person

Salman Khazaei

Position

Assistance professor

Latest degree

Ph.D.

Other areas of specialty/work

Epidemiology

Street address

Fahmideh street, Pajooheh Blvd, Hamadan City

City

Hamedan

Province

Hamadan

Postal code

6517838695

Phone

+98 81 3838 0548

Fax**Email**

salman.khazaei61@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Salman Khazaei

Position

Assistance professor

Latest degree

Ph.D.

Other areas of specialty/work

Epidemiology

Street address

Fahmideh street, Pajooheh Blvd, Hamadan City

City

Hamedan

Province

Hamadan

Postal code

6518325462

Phone

+98 81 3838 0548

Fax**Email**

salman.khazaei61@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Salman Khazaei

Position

Assistance professor

Latest degree

Ph.D.

Other areas of specialty/work

Epidemiology

Street address

Fahmideh street, Pajooheh Blvd, Hamadan City

City

Hamedan

Province

Hamadan

Postal code

6543125681

Phone

+98 81 3838 0548

Fax**Email**

salman.khazaei61@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available