Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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-19and 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

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Iran (Islamic Republic of)

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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 placcebo. 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
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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
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
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Position
Assistance professor
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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