Clinical Trial Protocol
Iranian Registry of Clinical Trials

31 May 2026

Evaluation of the effect of melatonin in the treatment of patients with COVID19 compared with placebo.

Protocol summary

Study aim
Determining the effects of melatonin in improving the condition of patients with COVID 19

Design
This study was performed on 100 COVID19 hospitalized patients . Randomization block balance method is used for randomization.Patients are divided into case and control groups. In this study, patients were given melatonin (10 mg) and placebo in pill form the night before bed for at least seven nights. In general, patients in the placebo group receive therapeutic drugs according to the national protocol + placebo, and the melatonin group receives therapeutic drugs according to the national protocol + melatonin. Trial phase is 3.

Settings and conduct
This study is performed in 100 patients with severe COVID19 admitted to the ICUs of Rasool Akram Hospital. The two randomly selected case and control groups receive the drug and placebo for at least 7 days, respectively. The outcome assessor is the only person who know the drug or placebo. The course of inflammatory tests and clinical conditions are monitored for oxygenation.

Participants/Inclusion and exclusion criteria
Patients over 20 years who either have a COVID 19-positive PCR, or a CT scan that meets COVID 19 criteria, or both enter the study.Patients who need a ventilator or have severe underlying kidney or liver disease are excluded from the study.

Intervention groups
Patients over 20 years of age who either have a positive COVID19- PCR, or a CT scan match that is consistent with COVID19 or have both criteria are included in the study. They are divided into case and control groups and melatonin is prescribed to the case group. The placebo is given to the control group.

Main outcome variables
Assessment of melatonin effect on the treatment of patients with COVID19 who admitted to the ICU.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20210411050925N1**
Registration date: **2022-01-09, 1400/10/19**
Registration timing: **prospective**

Last update: **2022-01-09, 1400/10/19**
Update count: **0**

Registration date
2022-01-09, 1400/10/19

Registrant information

Name
maryam roham

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 21 4411 2633

Email address
rohammm86@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-02-20, 1400/12/01

Expected recruitment end date
2022-05-20, 1401/02/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

Evaluation of the effect of melatonin in the treatment of patients with COVID19 compared with placebo.

Public title
Evaluation of the effect of melatonin on COVID 19
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients with positive RT-PCR for COVID19 Ability to sign consent and sufficient literacy No history of melatonin use during the study Admission in ICU Age over 20 years
Exclusion criteria:
Other systemic diseases (such as uncontrollable hypertension, uncontrolled diabetes, depression, elevated liver enzymes more than 3 times normal, cirrhosis, chronic kidney disease with GFR less than 30 cc / min) Allergy to melatonin Usage of anticoagulants such as warfarin or heparin with therapeutic doses Under mechanical ventilation
Age
From **20 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider
- Investigator
- Data analyser

Sample size
Target sample size: **100**
Randomization (investigator's opinion)
Randomized
Randomization description
-Randomization Block Balance Randomization: 25 blocks of 4 are designed, in each block 2 items are in group a and 2 items are in group b. The order of patients in blocks will be different.
Blinding (investigator's opinion)
Double blinded
Blinding description
The drug and placebo are at the disposal of the outcome assessor and are divided according to the description of the randomization section and provided to the clinical caregiver / researcher (physician). The clinician does not know the contents of the envelope. The participant also does not know the nature of the drug / placebo. Finally, the information is collected by the outcome assessor and provided to the data analyzer.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Iran university of medical sciences
Street address
Broncoscopy Ward.7th floor.Rassol-Akram Hospital,Niayesh street,Sattarkhan street
City
Tehran
Province
Tehran
Postal code
1445613131
Approval date
2020-12-22, 1399/10/02
Ethics committee reference number
IR.IUMS.FMD.REC.1399.810

Health conditions studied

1

Description of health condition studied
covid 19
ICD-10 code
U07.0
ICD-10 code description
covid 19

Primary outcomes

1

Description
The inflammatory factors level.
Timepoint
At the beginning of the study and 5 day after starting the drug/placebo.
Method of measurement
Evaluation of blood levels of inflammatory factors.

2

Description
Total duration of hospitalization and ICU residency.
Timepoint
Determination of hospitalization date,admission to ICU,discharge from ICU,discharge from hospital.
Method of measurement
Reading the files.

3

Description
Oxygenation level.
Timepoint
Daily assessment of oxygenation from admission time till discharge.

Method of measurement
Pulse oxymetry

Secondary outcomes

1

Description
Measurement of CRP level as inflammatory marker.
Timepoint
At the beginning of the study and day 5 after starting the drug/placebo.
Method of measurement
Serum level measurement.

2

Description
Measurement of ESR level as inflammatory marker.
Timepoint
At the beginning of the study and day 5 after starting the drug/placebo.
Method of measurement
Serum level measurement.

3

Description
Measurement of LDH level as inflammatory marker.
Timepoint
At the beginning of the study and day 5 after starting the drug/placebo.
Method of measurement
Serum level measurement.

Intervention groups

1

Description
Intervention group: Melatonin tablets made by Simorgh Company (6 mg) per night are given to patients until the time of discharge from the ICU.
Category
Treatment - Drugs

2

Description
Control group: Placebo with the same form as melatonin will be given once a night.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Rasool Akram hospital
Full name of responsible person
Hale Afshar
Street address
Bronchoscopy Ward, 7th floor, Rassol-Akram Hospital, Niayesh street, Sattarkhan street, Shahrara.
City
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afshar.hale@gmail.com
Web page address
https://hrmc.iums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Dr Abbas Motavalian
Street address
Iran University of Medical Sciences,Shahid Hemmat Highway,Tehran,Iran
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۱۴۴۹۶۱۴۵۳۵
Phone
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research-m@iums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Iran 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

Iran University of Medical Sciences
Full name of responsible person
Maryam Roham
Position
Assistant professor
Latest degree
Specialist
Other areas of specialty/work
Infectious diseases
Street address
Behafarin
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Person responsible for scientific inquiries

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Person responsible for updating data

Contact
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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
No - There is not 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
No - There is not a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available
Title and more details about the data/document
The clinical trial report will eventually be published as an article
When the data will become available and for how long
end of clinical trial
To whom data/document is available
All researchers and physicians
Under which criteria data/document could be used
Most of the data will be available after coordination with the project manager.
From where data/document is obtainable
Dr.Hale Afshar afshar.hale@gmail.com Bronchoscopy ward, Rasool Akram Hospital.
What processes are involved for a request to access data/document
The initial request will be answered within a week.
Comments