

Clinical Trial Protocol

Iranian Registry of Clinical Trials

23 Feb 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

rohamm86@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

Bronchoscopy 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

Tehran

Province

Tehran

Postal code

1445613131

Phone

+98 21 6435 2486

Email

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

City

Tehran

Province

Tehran

Postal code

۱۴۴۹۶۱۴۵۳۵

Phone

+98 21 8670 2503

Email

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
City
Tehran
Province
Tehran
Postal code
۱۵۹۳۷۴۷۸۱۱
Phone
+98 21 8214 1000
Email
rohgam.m@iums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Maraym Roham
Position
Assistant professor
Latest degree
Specialist
Other areas of specialty/work
Infectious diseases
Street address
Behafarin
City
Tehran
Province
Tehran
Postal code
۱۵۹۳۷۴۷۸۱۱
Phone
+98 21 8214 1000
Email
rohgam.m@iums.ac.ir

Person responsible for updating data

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
City
Tehran
Province
Tehran
Postal code
۱۵۹۳۷۴۷۸۱۱
Phone
+98 21 8214 1000
Email
rohgam.m@iums.ac.ir

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