Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Evaluating the Effect of melatonin on mechanically ventilated COVID 19 patients in Intensive care unit

Protocol summary

Study aim
Evaluating the effect of melatonin as an adjuvant therapy on the mortality and the duration of mechanical ventilation in ICU admitted COVID 19 patients

Design
Permuted block randomization will be used to randomize patients in melatonin and control group. this is an open labeled study without blinding (phase 1 trial with 33 patients)

Settings and conduct
66 intubated patients with COVID-19 infection who admitted to the Intensive care unit (Baharloo hospital, Tehran) were randomized to receive either 21mg melatonin or placebo for 5 days. Patients Main outcomes are the duration of mechanical ventilation requirements, and mortality.

Participants/Inclusion and exclusion criteria
Inclusion critria: all COVID19 patients more than 18 years old at first day of intubation Excusion critria: hepatic failure- liver enzyme more than 5 time of upper normal limit

Intervention groups
Patients will be randomized to receive either melatonin or placebo

Main outcome variables
Main outcomes are the duration of mechanical ventilation requirements, and mortality.

General information

Reason for update

Acronym
BMCOVID

IRCT registration information
IRCT registration number: **IRCT20210225050495N1**
Registration date: **2021-10-01, 1400/07/09**
Registration timing: **registered_while_recruiting**
Last update: **2021-10-01, 1400/07/09**
Update count: **0**

Registration date
2021-10-01, 1400/07/09

Registrant information

Name
Hadiseh Hosamirudsari

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 21 6585 0011

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h-hosami@sina.tums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-08-11, 1400/05/20

Expected recruitment end date
2022-02-09, 1400/11/20

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluating the Effect of melatonin on mechanically ventilated COVID 19 patients in Intensive care unit

Public title
Evaluating the Effect of melatonin on mechanically ventilated COVID 19 patients

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

all covid-19 patients admitted to the ICU Mechanically ventilated patients within the first 24 hours of intubation

Exclusion criteria:

liver enzyme more than 5 times of normal upper limit

Age

From **18 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **66**

Randomization (investigator's opinion)

Randomized

Randomization description

patients were randomized using Allocation random software (version 2.0) trough random block sizes of 4 and 6 with an allocation ratio of 1:1, to receive either melatonin or placebo. this is an open labeled study without blinding

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

1

Registry name

Tehran university of medical sciences

Secondary trial Id

IR.TUMS.VCR.REC.1399.159

Registration date

2020-04-02, 1399/01/14

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tehran University of Medical Sciences

Street address

Baharloo hospital, Behdari avenue, Rah-Ahan square

City

Tehran

Province

Tehran

Postal code

12299

Approval date

2020-04-05, 1399/01/17

Ethics committee reference number

IR.TUMS.VCR.REC.1399.159

Health conditions studied

1

Description of health condition studied

critical COVID19

ICD-10 code

U07.1 COVI

ICD-10 code description

U07.1 COVID-19, virus identified

Primary outcomes

1

Description

In ICU Mortality Percent

Timepoint

At the end of the study

Method of measurement

The Number of Alive patients at the end of the study in each group

2

Description

the duration of the mechanical ventilation

Timepoint

at the end of the study

Method of measurement

Calculating the total days of mechanical ventilation

Secondary outcomes

empty

Intervention groups

1

Description

Patients in melatonin group will receive 21mg of melatonin (Razak) every night for 5 days through nasogastric tubr

Category

Treatment - Drugs

2

Description

Control group: Placebo group will receive placebo produced by Razak Company, every night for 5 nights

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Baharloo Hospital
Full name of responsible person
Hadiseh Hosamirudsari
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Baharloo hospital, Railway square, Behdari Ave,Tehrannue
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Mohammadali Sahraian
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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
Tehran 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
Tehran University of Medical Sciences
Full name of responsible person
Hadiseh Hosamirudsari
Position
Assistant Professor
Latest degree
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Person responsible for scientific inquiries

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Person responsible for updating data

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Full name of responsible person

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

there is no more data

Study Protocol

No - There is not 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

No - There is not a plan to make this available

Clinical Study Report

No - There is not 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