

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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 criteria: all COVID19 patients more than 18 years old at first day of intubation Exclusion criteria: 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

BMCVID

##### 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)

##### Phone

+98 21 6585 0011

##### Email address

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) through 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

**Street address**

Baharloo hospital, Railway square, Behdari Ave, Tehrannue

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baharloo@sina.tums.ac.ir

**Web page address**<https://baharloo.tums.ac.ir>**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Mohammadali Sahraian

**Street address**

Baharloo Hospital, Rah ahan Square, Behdari Avenue, Tehran, Rah ahan Square

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h-hosami@sina.tums.ac.ir

**Web page address**<https://bahaloo.tums.ac.ir>**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**

Specialist

**Other areas of specialty/work**

Infectious diseases

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**Web page address**<https://baharloo.tums.ac.ir>**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Nafiseh Sadat Alizadeh

**Position**

clinical pharmacologist

**Latest degree**

Specialist

**Other areas of specialty/work**

Medical Pharmacy

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Baharloo Hospital- Behdari street- rail way square

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**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Nafiseh Sadat Alizadeh

**Position**

clinical pharmacologist

**Latest degree**

Specialist

**Other areas of specialty/work**

Medical Pharmacy

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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