

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

27 Jun 2026

### Evaluation of the effect of melatonin in patients with COVID-19-induced pneumonia admitted to the Intensive Care Unit

#### Protocol summary

##### Study aim

Evaluation of the effect of melatonin in patients with COVID-19-induced pneumonia admitted to the Intensive Care Unit

##### Design

Controlled clinical trial with parallel group, open-label, phase 3, 60 patients, block randomized method.

##### Settings and conduct

This study will be conducted at the Intensive Care Unit of Shahid Mohammadi Hospital, Hormozgan University of Medical Sciences, Bandar Abbas. The study population is 60 patients with COVID-19 (30 patients in control group and 30 in study group).

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Definitive diagnosis of COVID-19 based on RT-PCR or/and serological testing, age >20 years, Diagnosis of pneumonia based on pulmonary CT-Scan, admitted in the intensive care unit, signing informed consent and willingness of study participant to accept randomization to any assigned treatment arm. Exclusion criteria: Patients with underlying disorder, including convulsive disorders, hepatic disease and disorder, renal disease and disorder, intubated patients and use of mechanical ventilation, pregnancy and breastfeeding.

##### Intervention groups

Group A will be patients receiving standard treatment of COVID-19 according to the Ministry of Health's protocol. Group B will be patients receiving, in addition to the standard treatment, Melatonin capsules, at a dose of 5mg twice a day for a period of seven days.

##### Main outcome variables

Checking of ABG, CBC, C-RP, Ferritin, and LDH. Evaluation the need for mechanical ventilation, consciousness, and mortality rate.

#### General information

##### Reason for update

##### Acronym

#### IRCT registration information

IRCT registration number: **IRCT20200506047323N7**

Registration date: **2021-02-16, 1399/11/28**

Registration timing: **prospective**

Last update: **2021-02-16, 1399/11/28**

Update count: **0**

#### Registration date

2021-02-16, 1399/11/28

#### Registrant information

##### Name

Mohammad Fathalipour

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 76 3371 0406

##### Email address

m.fathalipour@hums.ac.ir

#### Recruitment status

**Recruitment complete**

#### Funding source

#### Expected recruitment start date

2021-02-28, 1399/12/10

#### Expected recruitment end date

2021-08-01, 1400/05/10

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

Evaluation of the effect of melatonin in patients with COVID-19-induced pneumonia admitted to the Intensive Care Unit

**Public title**

melatonin in patients with COVID-19

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Definitive diagnosis of COVID-19 based on RT-PCR or/and serological testing, Age >20 years. Diagnosis of pneumonia based on pulmonary CT-Scan. Admitted in the intensive care unit. Signing informed consent and willingness of study participant to accept randomization to any assigned treatment arm.

**Exclusion criteria:**

Patients with underlying disorder, including convulsive disorders, hepatic disease and disorder, renal disease and disorder. Intubated patients and use of mechanical ventilation. pregnancy and breastfeeding.

**Age**

From **20 years** old

**Gender**

Both

**Phase**

3

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **60**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Block randomization will be performed (each block consists 6 patients). Allocation sequence and concealment codes will be generated using [www.sealedenvelope.com](http://www.sealedenvelope.com). The closed envelope method will be used to hide the allocation sequence.

**Blinding (investigator's opinion)**

Not blinded

**Blinding description****Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics committee of Hormozgan University of Medical Sciences

**Street address**

Jomhuri Eslami Blvd

**City**

Bandar Abbas

**Province**

Hormozgan

**Postal code**

7919915519

**Approval date**

2021-02-02, 1399/11/14

**Ethics committee reference number**

IR.HUMS.REC.1399.526

**Health conditions studied****1****Description of health condition studied**

COVID-19 disease

**ICD-10 code**

U07.2

**ICD-10 code description**

COVID-19, virus not identified

**Primary outcomes****1****Description**

Arterial blood gas (ABG)

**Timepoint**

Before intervention and daily during the intervention

**Method of measurement**

Biochemical laboratory

**2****Description**

C-Reactive Protein (C-RP)

**Timepoint**

Before intervention and 3, 5, 7 days after the start of the intervention

**Method of measurement**

C-RP kit

**3****Description**

Ferritin

**Timepoint**

Before intervention and 3, 5, 7 days after the start of the intervention

**Method of measurement**

Biochemical laboratory

**4****Description**

Lactate dehydrogenase (LDH)

**Timepoint**

Before intervention and 3, 5, 7 days after the start of the intervention

**Method of measurement**

Biochemical laboratory

**Secondary outcomes**

## 1

### Description

Need for mechanical ventilation

### Timepoint

Daily

### Method of measurement

Checklist

## 2

### Description

Patients consciousness level

### Timepoint

Daily

### Method of measurement

Glasgow Coma Scale (GCS)

## 3

### Description

Mortality rate

### Timepoint

Daily

### Method of measurement

Checklist

## Intervention groups

### 1

#### Description

Control group: Group A will be patients receiving standard treatment of COVID-19 according to the Ministry of Health's protocol.

#### Category

Treatment - Drugs

### 2

#### Description

Intervention group: Group B will be patients receiving, in addition to the standard treatment, Melatonin capsules, at a dose of 5mg twice a day for a period of seven days.

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Shahid Mohammadi Hospital

##### Full name of responsible person

Manoochehr Kamali

##### Street address

Jomhuri Eslami Blvd

##### City

Bandar Abbas

##### Province

Hormozgan

##### Postal code

7919915519

##### Phone

+98 76 3334 5003

##### Email

Manuchehr.kamali@yahoo.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Bandare-abbas University of Medical Sciences

##### Full name of responsible person

Teamur Aghamolaei

##### Street address

Jomhuri Eslami Blvd

##### City

Bandar Abbas

##### Province

Hormozgan

##### Postal code

7919915519

##### Phone

+98 76 3333 3280

##### Fax

+98 76 3334 6994

##### Email

mail@hums.ac.ir

##### Web page address

<http://hums.ac.ir/>

#### Grant name

#### Grant code / Reference number

#### Is the source of funding the same sponsor organization/entity?

Yes

#### Title of funding source

Bandare-abbas 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

Bandare-abbas University of Medical Sciences

##### Full name of responsible person

Mohammad Fathalipour

##### Position

Assistant professor

##### Latest degree

Ph.D.

##### Other areas of specialty/work

Medical Pharmacy  
**Street address**  
Emam Hossein Blvd  
**City**  
Bandar Abbas  
**Province**  
Hormozgan  
**Postal code**  
7919691982  
**Phone**  
+98 76 3371 0406  
**Fax**  
+98 76 3371 0389  
**Email**  
m.fathalipour@hums.ac.ir

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
Bandare-abbas University of Medical Sciences  
**Full name of responsible person**  
Manoochehr Kamali  
**Position**  
Associate professor  
**Latest degree**  
Specialist  
**Other areas of specialty/work**  
Anesthesiology  
**Street address**  
Jomhuri Eslami Blvd  
**City**  
Bandar Abbas  
**Province**  
Hormozgan  
**Postal code**  
7919915519  
**Phone**  
+98 76 3334 5003  
**Fax**  
+98 76 3334 5003  
**Email**  
shmh@hums.ac.ir  
**Web page address**  
<http://shmh.hums.ac.ir/>

## Person responsible for updating data

### Contact

**Name of organization / entity**  
Bandare-abbas University of Medical Sciences  
**Full name of responsible person**  
Ali Ameri  
**Position**  
PharmD Student  
**Latest degree**  
Master

### Other areas of specialty/work

Medical Pharmacy  
**Street address**  
Jomhuri Eslami Blvd  
**City**  
Bandar Abass  
**Province**  
Hormozgan  
**Postal code**  
7919915519  
**Phone**  
+98 76 3334 7000  
**Fax**  
+98 76 3334 5003  
**Email**  
a.ameri.ph@gmail.com

## 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

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

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

Information regarding the study outcomes will be shared.

### When the data will become available and for how long

Data will become available after publication of obtained results.

### To whom data/document is available

Only academic institutions

### Under which criteria data/document could be used

The study protocol or proposal should be approved by Ethics committee of institutions. The rights of authors and sponsors should be respected

### From where data/document is obtainable

M.fathalipour@hums.ac.ir A.ameri.ph@gmail.com

### What processes are involved for a request to access data/document

Requests should be addressed to the Technology and Research Vice-chancellery of Hormozgan University of Medical Sciences and the project executor should be informed.

### Comments