# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

10 Sep 2026

## Evaluation of the efficacy and safety of Melatonin in patients with COVID-19: a randomized clinical trial

### Protocol summary

**Study aim**
Evaluation of the efficacy and safety of Melatonin in patients with COVID-19

**Design**
A phase 3, Placebo-controlled, Paralleled, double-blind, randomized clinical trial, 60 patients, randomized using blocks

**Settings and conduct**
This study will be conducted at the 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: Age >20 years, positive polymerase chain reaction (PCR) test for COVID-19 or/and lung involvement in imaging, primary clinical symptoms, hspitalized and moderate patients, and signing informed consent. Exclusion Criteria: Patients with underlying diseases including hypertension, diabetes, seizure, depression, chronic hepatitis, cirrhosis, and cholestatic liver diseases, use of anticoagulant drugs like warfarin, hormonal drugs, alcohol, and any illegal drugs (during last 30 days), history of allergy to Melatonin, and 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 50 mg daily for a period of seven days.

**Main outcome variables**
Checking the fever, respiratory rate, Oxygen saturation Evaluation of white blood cell count, C-reactive protein Occurrence of adverse drug reactions

### General information

**Reason for update**

**Acronym**

**IRCT registration information**
IRCT registration number: **IRCT20200506047323N5**
Registration date: **2020-08-14, 1399/05/24**
Registration timing: **prospective**

Last update: **2020-08-14, 1399/05/24**
Update count: **0**

**Registration date**
2020-08-14, 1399/05/24

**Registrant information**

**Name**
Mohammad Fathalipour

**Name of organization / entity**

**Country**
Iran (Islamic Republic of)

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**Recruitment status**
**recruiting**

**Funding source**

**Expected recruitment start date**
2020-08-22, 1399/06/01

**Expected recruitment end date**
2641-11-22, 2020/09/01

**Actual recruitment start date**
empty

**Actual recruitment end date**
empty

**Trial completion date**
empty

**Scientific title**
Evaluation of the efficacy and safety of Melatonin in patients with COVID-19: a randomized clinical trial

**Public title**
Melatonin in COVID-19
**Purpose**
Treatment
**Inclusion/Exclusion criteria**
**Inclusion criteria:**
Age >20 years Positive polymerase chain reaction (PCR) test for COVID-19 or/and lung involvement in imaging Primary clinical symptoms Hospitalized and moderate patients Signing informed consent and willingness of study participant to accept randomization to any assigned treatment arm
**Exclusion criteria:**
Patients with underlying diseases including hypertension, diabetes, seizure, depression, chronic hepatitis, cirrhosis, and cholestatic liver diseases Use of anticoagulant drugs like warfarin, hormonal drugs, alcohol, and any illegal drugs (during last 30 days) History of allergy to Melatonin Pregnancy and breastfeeding
**Age**
From **20 years** old
**Gender**
Both

**Phase**
3
**Groups that have been masked**

- Participant
- Care provider
- Data analyser

**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. The closed envelope method will be used to hide the allocation sequence.
**Blinding (investigator's opinion)**
Double blinded
**Blinding description**
The medication and placebo will be coded by the project manager. Patients will be randomly allocated within the blocks based on the hidden codes, and study participants, physicians, and nurses who evaluate the outcomes will be blind to the intervention and studied groups.
**Placebo**
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**
2020-08-02, 1399/05/12
**Ethics committee reference number**
IR.HUMS.REC.1399.250

## 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**
Body temperature
**Timepoint**
Before intervention and daily during the study
**Method of measurement**
Thermometer

**2**

**Description**
Respiratory rate
**Timepoint**
Before intervention and daily during the study
**Method of measurement**
Respiratory Count

**3**

**Description**
Oxygen saturation
**Timepoint**
Before intervention and daily during the study
**Method of measurement**
Pulse oximeter

## Secondary outcomes

**1**

**Description**
Lymphocytopenia
**Timepoint**
Before intervention and 7 days after the start of the intervention
**Method of measurement**
Cell count

**2**

**Description**
C-reactive protein
**Timepoint**
Before intervention and 7 days after the start of the intervention
**Method of measurement**
C-RP kit

**3**

**Description**
Incidence of serious adverse events
**Timepoint**
Before intervention and daily during the study
**Method of measurement**
Questionnaire

## Intervention groups

**1**

**Description**
Intervention group: The standard treatment for COVID-19 based on the Ministry of Health's protocol including hydroxychloroquine sulfate (Amin Pharmaceutical company, Isfahan) at a dose of 400 mg twice a day for the first day and 200 mg twice a day for six following days, along with melatonin capsules (Vana Darou Gostar Pharmaceutical Company, Iran) at a dose of 50 mg once a day for a period of seven days.
**Category**
Treatment - Drugs

**2**

**Description**
Control group: Hydroxychloroquine sulfate (Amin Pharmaceutical company, Isfahan) at a dose of 400 mg twice a day for the first day and 200 mg twice a day for six following days, along with melatonin-like placebo capsules (Vana Darou Gostar Pharmaceutical Company, Iran) at a dose of one capsule daily 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**
Parivash Davoodian
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Jomhuri Eslami Blvd
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## Sponsors / Funding sources

**1**

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**Name of organization / entity**
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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
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Ph.D.
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Medical Pharmacy
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## Person responsible for scientific inquiries

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## Person responsible for updating data

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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**
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@yahoo.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 informed.

**Comments**