Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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)

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+98 76 3371 0406

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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. 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
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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
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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
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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
Ali Ameri
Position
PharmD Student
Latest degree
Master
Other areas of specialty/work
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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@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 informed.
Comments