

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Aug 2022

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. 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

Contact

Name of organization / entity
Bandare-abbas University of Medical Sciences
Full name of responsible person
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Person responsible for updating data

Contact

Name of organization / entity
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Ali Ameri
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PharmD Student
Latest degree
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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 be informed.

Comments