Clinical Trial Protocol
Iranian Registry of Clinical Trials

05 Jun 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

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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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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Bandare-abbas University of Medical Sciences
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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
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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