Clinical Trial Protocol
Iranian Registry of Clinical Trials

30 May 2026

Evaluation of adding melatonin to routine treatment on outcomes and quality of sleep in COVID-19 patients

Protocol summary

Study aim
Determination of the addition of melatonin to routine treatment on treatment outcomes and the quality of sleep in COVID-19 patients
Design
The present study will be a clinical trial study with a parallel design and without blinding.
Settings and conduct
The study will be conducted in Imam Khomeini Hospital of Sari. The first group, in addition to the usual treatment, which includes chloroquine azithromycin and supportive measures, will receive melatonin tablets in the amount of 3 mg at night for 7 days. in this study blindness wont be done The second group will receive the usual treatment.
Participants/Inclusion and exclusion criteria
Inclusion criteria: This study will be performed on patients with the new coronavirus (CoV-2019). Subjects will be confirmed using CT scan or PCR findings and will then be included in the study. Exclusion criteria: Patients who are not confirmed by CT scan and PCR findings will not be included in the study.
Intervention groups
Intervention group: chloroquine + azithromycin + supportive measures + melatonin tablets in the amount of 3 mg at night for 7 days. Control group: will receive the usual treatment.
Main outcome variables
1- Time to stop the fever 2- Transfer to ICU 3- Mortality 4- Sleep quality

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20200411047030N1**
Registration date: **2020-04-17, 1399/01/29**
Registration timing: **registered_while_recruiting**
Last update: **2020-04-17, 1399/01/29**
Update count: **0**
Registration date
2020-04-17, 1399/01/29

Registrant information
Name
Reza Alizadeh-Navaei
Name of organization / entity
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2020-04-14, 1399/01/26
Expected recruitment end date
2020-06-15, 1399/03/26
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluation of adding melatonin to routine treatment on outcomes and quality of sleep in COVID-19 patients

Public title
The effect of melatonin on the quality of sleep in COVID-19 patients
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:

Consent to attend the study Clinical symptoms Lymphocyte count less than 1100 Positive CT scan or C-reactive protein

Exclusion criteria:

Epilepsy Taking warfarin and other anticoagulants and coagulation disorders Uncontrolled diabetes and high blood pressure

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **82**

Randomization (investigator's opinion)

N/A

Randomization description

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 Mazandaran University of Medical Sciences

Street address

Moallem Square, Deputy of Research and Technology, Mazandaran University of Medical Sciences

City

Sari

Province

Mazandaran

Postal code

4817844718

Approval date

1920-04-12, 1299/01/23

Ethics committee reference number

IR.MAZUMS.REC.1399.056

Health conditions studied

1

Description of health condition studied

COVID-19

ICD-10 code

B34.2

ICD-10 code description

Coronavirus infection, unspecified

Primary outcomes

1

Description

Stop the fever

Timepoint

It will be reviewed for 7 days from the study onset.

Method of measurement

It is recorded by a thermometer.

2

Description

Transfer to ICU

Timepoint

A maximum of 10 days of hospitalization will be checked.

Method of measurement

Tracking hospitalized patients through questions and recording in questionnaires

3

Description

Mortality

Timepoint

A maximum of 10 days of hospitalization will be checked.

Method of measurement

Tracking hospitalized patients through questions and recording in questionnaires

4

Description

Sleep quality

Timepoint

Days 1, 2, 3, and 7.

Method of measurement

The Leeds Sleep Evaluation questionnaire will be used.

Secondary outcomes

1

Description

Lymphopenia status

Timepoint

It will be reviewed on the first day and day 7.

Method of measurement

Cell counter device

2

Description

C-reactive protein status

Timepoint

It will be reviewed on the first day and day 7.

Method of measurement
Serology test

3

Description
Peripheral capillary oxygen saturation (SPO2)
Timepoint
It will be reviewed on the first day and day 7.
Method of measurement
Pulse Oximeter

Intervention groups

1

Description
Intervention group: COVID-19 patients receiving hydroxychloroquine (200 mg every 12 hours), azithromycin (500 mg daily) and melatonin tablets (3 mg every night before bedtime) for up to 7 days
Category
Treatment - Drugs

2

Description
Control group: COVID-19 patients receiving hydroxychloroquine (200 mg every 12 hours) and azithromycin (500 mg daily) for up to 7 days.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Khomeini Educational and Medical Hospital in Sari
Full name of responsible person
Reza Alizadeh-Navaei
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Razi Street
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mazandaran University of Medical Sciences
Full name of responsible person
Prof. Majid Saeedi
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Moallem Square
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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
Mazandaran 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
Mazandaran University of Medical Sciences
Full name of responsible person
Seyed Abbas Mousavi
Position
Associate professor
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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
Undecided - It is not yet known if there will be 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
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Yes - There is a plan to make this available

Data Dictionary
Not applicable

Title and more details about the data/document
The SPSS data file can be published

When the data will become available and for how long
After publication

To whom data/document is available
Researchers

Under which criteria data/document could be used
Use for review studies

From where data/document is obtainable
Corresponding author E-mail

What processes are involved for a request to access data/document
Sending E-mail

Comments