

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

Country

Iran (Islamic Republic of)

Phone

+98 11 3325 7230

Email address

alizadeh@mazums.ac.ir

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

Street address

Razi Street

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Mazandaran

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4816633131

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Email

reza_nava@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Prof. Majid Saeedi

Street address

Moallem Square

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4817844718

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msaeedi@mazums.ac.ir

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

Latest degree

Specialist

Other areas of specialty/work

Psychiatrics

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Person responsible for updating data

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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

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