

Clinical Trial Protocol

Iranian Registry of Clinical Trials

23 Feb 2026

Evaluation of melatonin tablet efficacy as an adjuvant treatment for patients with mild to moderate COVID-19 in Qaem and Imam Reza Hospital, Mashhad: A triple-blind randomized placebo controlled clinical trial

Protocol summary

Study aim

Evaluation of the melatonin efficacy as a supplement for treatment of mild to moderate COVID-19

Design

This is a randomized triple-blind, parallel group clinical trial on 40 patients with mild to moderate covid-19 (20 patients in treatment group and 20 patients in placebo group).

Settings and conduct

This study will be performed on 40 patients with clinical or laboratory diagnosis of mild to moderate COVID-19 who refer to Quem or Imam Reza Hospital, Mashhad, Iran. They will received three melatonin 3mg tablet daily for 2 weeks in treatment group or three placebo tablet in placebo group.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Laboratory or radiological or clinical diagnosis of mild to moderate COVID-19, age between 18-85y, sign of the written consent Non-including criteria: pregnancy or lactation, history of allergy to melatonin, concomitant use of alcohol or strong 1A2 inhibitors, immunosuppression, lactase deficiency

Intervention groups

Treatment group: three melatonin 3mg tablet daily for 2 weeks Control group: three placebo tablet daily for two weeks

Main outcome variables

Primary endpoints of the study are rates of treatment response and adverse drug reactions. Secondary endpoints are duration of hospitalization and patients' clinical outcomes.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200408046990N12**

Registration date: **2022-11-15, 1401/08/24**

Registration timing: **registered_while_recruiting**

Last update: **2022-11-15, 1401/08/24**

Update count: **0**

Registration date

2022-11-15, 1401/08/24

Registrant information

Name

Sepideh Elyasi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3180 1588

Email address

elyasis@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-10-25, 1401/08/03

Expected recruitment end date

2023-10-25, 1402/08/03

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of melatonin tablet efficacy as an adjuvant

treatment for patients with mild to moderate COVID-19 in Qaem and Imam Reza Hospital, Mashhad: A triple-blind randomized placebo controlled clinical trial

Public title

Evaluation of the melatonin tablet efficacy as an adjuvant therapy for patients with mild to moderate COVID-19

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Clinical or laboratory diagnosis of mild to moderate COVID-19 Age between 18-85 y Sign of written consent

Exclusion criteria:

Pregnancy and lactation History of allergy to melatonin Immunosuppression history Lactase deficiency Concomitant use of alcohol and 1A2 inhibitors

Age

From **18 years** old to **85 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Blocked randomization using website <https://www.sealedenvelope.com> With the explanation that each block has 4 members and the shape of the blocks can be as follows: [ABAB], [ABBA], [AABB],[BBAA],[BABA][BAAB] Code A belongs to the intervention group and code B belongs to the control group. the mentioned website selects 10 blocks from Quadruple blocks and patients will be assigned to blocks in the order of entry into the study and finally 40 patients will enter the study.

Blinding (investigator's opinion)

Triple blinded

Blinding description

The melatonin and the placebo tablets will be packaged in identical-looking bottle and delivered to the clinician. Patients who meet the inclusion criteria will be selected by clinician to be included in the study, randomly assigned to a drug or placebo group and given a bottle with A or B mark. Patients will be evaluated in the course of treatment by the physician and the pharmacy student. Data collection and analysis will be performed by the pharmacy student and the clinical pharmacist. All of them will be unaware that A or B is on medication or placebo until the end of the study and data analysis.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Mashhad University of Medical Sciences

Street address

Qureshi Building, Daneshgah street

City

Mashhad

Province

Razavi Khorasan

Postal code

1394491388

Approval date

2020-05-16, 1399/02/27

Ethics committee reference number

IR.MUMS.REC.1399.354

Health conditions studied

1

Description of health condition studied

COVID-19 pneumonia

ICD-10 code

U07.1

ICD-10 code description

COVID-19, virus identified

Primary outcomes

1

Description

Fever

Timepoint

Daily

Method of measurement

Thermometer

2

Description

Clinical response to the treatment (including improvement of cough, myalgia, headache, olfactory and taste disorders)

Timepoint

Daily

Method of measurement

Based on patients examination and interview

3

Description

Radiologic improvement

Timepoint

Two weeks after treatment

Method of measurement

Lung CT scan

4

Description

Laboratory response

Timepoint

Weekly

Method of measurement

Assessment of lymphocyte count

5

Description

Drug adverse reaction

Timepoint

Daily

Method of measurement

Patient file and interview

Secondary outcomes

1

Description

Duration of the hospitalization

Timepoint

End of the treatment

Method of measurement

Patient's file

2

Description

Patient's final outcome

Timepoint

End of the treatment

Method of measurement

Patient's file

Intervention groups

1

Description

Intervention group: three melatonin 3mg tablet daily for two weeks

Category

Treatment - Drugs

2

Description

Control group: placebo with same appearance of melatonin tablet three daily for 2 weeks

Category

Placebo

Recruitment centers

1

Recruitment center**Name of recruitment center**

Quem hospital

Full name of responsible person

Sepideh Hejazi

Street address

Quem Hospital, Ahmadabad Ave., Mashhad, Iran

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2

Recruitment center**Name of recruitment center**

Imam Reza hospital

Full name of responsible person

Sepideh Hejazi

Street address

Imam reza Square, Ebne-sina Street

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Email

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Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

Mashhad University of Medical Sciences

Full name of responsible person

Majid Ghayour-mobarhan

Street address

Faculty of Medicine, Ferdowsi University, Vakilabad Boulevard

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Email

ghayourm@mums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Mashhad 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

Mashhad University of Medical Sciences

Full name of responsible person

Sepideh Elyasi

Position

Associate Professor

Latest degree

Specialist

Other areas of specialty/work

Medical Pharmacy

Street address

Faculty of Pharmacy; Ferdowsi University; Vakilabad Boulevard

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

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Position

Associate Professor

Latest degree

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Other areas of specialty/work

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Person responsible for updating data

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Name of organization / entity

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

No more information is 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

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

Undecided - It is not yet known if there will be a plan to

make this available
Data Dictionary

Undecided - It is not yet known if there will be a plan to
make this available