Clinical Trial Protocol
Iranian Registry of Clinical Trials

06 Nov 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, immunosuppresion, 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
City
Mashhad
Province
Razavi Khorasan
Postal code
9137913316
Phone
+98 51 3180 1588
Email
hejazis@mums.ac.ir

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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hejazis@mums.ac.ir

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
City
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Province
Razavi Khorasan
Postal code
17871 91886
Phone

+98 51 3841 1538

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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elyasis@mums.ac.ir

Person responsible for scientific 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

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Person responsible for updating data

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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