

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 Aug 2026

Study of therapeutic effect of melatonin in patients with COVID-19 : a double-blind randomized clinical trial

Protocol summary

Study aim

the aim of this Study is to evaluate the therapeutic effect of melatonin in patients with COVID-19 admitted to Rasht Razi Hospital

Design

A phase 2/3 randomized, double blinded, controlled clinical trial with a parallel group design of 96 patients

Settings and conduct

96 Patients with COVID-19 admitted to Razi Hospital in Rasht with a positive RT-PCR test for SARS-CoV-2 will enter the study. 32 patients will receive placebo and two groups (32 in each) will receive 6 mg and 12 mg of melatonin, per night for 5 times, respectively. Outcomes will be recorded on morning of the first (day before the intervention), fourth and sixth day. Participants, clinician, researcher, outcome assessor, analyst, and at the beginning of the study the safety monitoring committee and data except clinical pharmacist (responsible for randomization) don't know which arm the participant is assigned to and will be blind to the allocation of melatonin and placebo. Placebo tablets will be similar in shape, size and color to melatonin

Participants/Inclusion and exclusion criteria

Patients with moderate to severe whose PCR test is positive for SARS-CoV will be included in the study. Inclusion Criteria for patients with moderate symptoms: evidence of lower respiratory disease (dyspnea, Chest compression, ...) oxygen saturation (SpO₂) between 90 to 93% and lung infiltrates < 50%. criteria for patients with severe symptoms: Dyspnea, respiratory frequency > 30 breaths/min, oxygen saturation (SpO₂) < 90%, PaO₂/FiO₂ < 300 mm Hg and lung infiltrates > 50%.

Intervention groups

For all patients, there are standard protocols for the treatment of existing Covid 19 patients. In the placebo group, placebo tablets and in the intervention groups, 6 and 12 mg of melatonin are given as adjuvant

Main outcome variables

the level of CRP ESR, ICU requirement, hospitalization or death, and number of days hospitalized

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210505051197N1**

Registration date: **2021-07-18, 1400/04/27**

Registration timing: **prospective**

Last update: **2021-07-18, 1400/04/27**

Update count: **0**

Registration date

2021-07-18, 1400/04/27

Registrant information

Name

Malek Moien Ansar

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 13 3369 0884

Email address

ansarmoien@gums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-07-24, 1400/05/02

Expected recruitment end date

2022-02-18, 1400/11/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Study of therapeutic effect of melatonin in patients with COVID-19 : a double-blind randomized clinical trial

Public title

Melatonin and Covid-19

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

RT-PCR test positive for SARS-CoV-2 criteria for patients with moderate symptoms: evidence of lower respiratory disease(dyspnea, Chest compression ,..) oxygen saturation (SpO2) between 90 to 93% lung infiltrates <50% criteria for patients with severe symptoms: Dyspnea respiratory frequency >30 breaths/min oxygen saturation (SpO2) < 90% and PaO2/FiO2 <300 mm Hg lung infiltrates >50%

Exclusion criteria:

patients with mild symptoms diabetes hypertension pregnant women those who have already been in clinical trial with other drugs. Age less than 18 years

Age

From **18 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **96**

Randomization (investigator's opinion)

Randomized

Randomization description

Block randomization method will be used for random assignment to intervention and control groups (each block includes 6 patients). assigned sequences and hidden codes are generated using www.sealedenvelope.com. The closed envelope method will be used to hide the sequence

Blinding (investigator's opinion)

Double blinded

Blinding description

Participants , clinician, researcher, outcome assessor, data analyst except clinical pharmacist (responsible for randomization) don't know which arm the participant is assigned to and will be blind to the allocation of melatonin and placebo. Placebo tablets will be similar in shape, size and color to melatonin. At the beginning of the study the safety monitoring committee and data on the allocation of melatonin and placebo will be blind .In case of any serious complications in the participants or

significant differences in the study groups, the code of the participants or study groups will be decoded at the request of the above committee. Hidden codes are generated using www.sealedenvelope.com. The closed envelope method will be used to hide the assigned sequence

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Guilan University of Medical Sciences

Street address

Deputy of university Research and Technology of the University

City

Rasht

Province

Guilan

Postal code

1376941996

Approval date

2021-04-21, 1400/02/01

Ethics committee reference number

IR.GUMS.REC.1400.035

Health conditions studied**1****Description of health condition studied**

covid-19

ICD-10 code

U07.01

ICD-10 code description

COVID-19 Disease

Primary outcomes**1****Description**

C-Reactive Protein serum levels

Timepoint

Morning of the first day (before the intervention), fourth day (day after the third intervention) and sixth day (day after the last intervention)

Method of measurement

By ELISA

2

Description

erythrocyte sedimentation rate serum levels

Timepoint

Morning of the first day (before the intervention), fourth day (day after the third intervention) and sixth day (day after the last intervention)

Method of measurement

erythrocyte sedimentation rate per hour

Secondary outcomes

1

Description

Outcome of the disease

Timepoint

Morning of the first day (before the intervention), fourth day (day after the third intervention) and sixth day (day after the last intervention)

Method of measurement

Reduction of clinical sign and symptoms, no need for supplemental oxygen or mechanical ventilation

2

Description

ferritin

Timepoint

Morning of the first day (before the intervention), fourth day (day after the third intervention) and sixth day (day after the last intervention)

Method of measurement

by ELISA

3

Description

VitD(25OH)

Timepoint

Morning of the first day (before the intervention), fourth day (day after the third intervention) and sixth day (day after the last intervention)

Method of measurement

by ELISA

4

Description

Days of hospitalization

Timepoint

Until discharge or death

Method of measurement

Based on the days of hospitalization

Intervention groups

1

Description

Intervention group1: 6 mg Melatonin (2 tablets of 3 mg melatonin made by Simorgh Pharmaceutical Company) is

given orally every night for 5 nights

Category

Treatment - Other

2

Description

Intervention group2: 12 mg of melatonin (4 tablets of 3 mg melatonin made by Simorgh Pharmaceutical Company) is given orally every night for 5 nights

Category

Treatment - Other

3

Description

Control group: receiving placebo(4 placebo tablets containing starch, magnesium stearate, calcium carbonate and maltodextrin made by the Faculty of Pharmacy of Guilan University of Medical Sciences) is given orally every night for 5 nights.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Razi Hospital

Full name of responsible person

Tofigh Yaghobi

Street address

Razi Hospital-Sardare Jangal Boulevard

City

Rasht

Province

Guilan

Postal code

4144895655

Phone

+98 13 3355 0028

Email

tofigh_yaghubi@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Rasht University of Medical Sciences

Full name of responsible person

Dr Mohammadreza Naghipour

Street address

Guilan University of Medical Sciences. 17 shahrivar street

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Province

Guilan

Postal code
66949-41446

Phone
+98 13 3333 5820

Email
research@gums.ac.ir

Grant name

Grant code / Reference number

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

Title of funding source
Rasht 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
Rasht University of Medical Sciences

Full name of responsible person
Malek Moien Ansar

Position
Associate professor

Latest degree
Ph.D.

Other areas of specialty/work
Biochemistry

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Person responsible for scientific inquiries

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Position

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Person responsible for updating data

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Position
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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

Yes - There is 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

Not applicable

Title and more details about the data/document

After collecting and analyzing the data, the results are available to the public in the form of articles

When the data will become available and for how long

after publication and for 6 months

To whom data/document is available

people working in academic institutions

Under which criteria data/document could be used

There are no restrictions

From where data/document is obtainable

Dr Malek Moien Ansar

What processes are involved for a request to access data/document

Request to Deputy of university Research and Technology of the University and the project supervisor

Comments