Clinical Trial Protocol
Iranian Registry of Clinical Trials

05 Jul 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 whoes 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 و..) oxygen saturation (SpO2) between 90 to 93% and lung infiltrates<50%. criteria for patients with sever 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 و..) oxygen saturation (SpO2) between 90 to 93% lung infiltrates<50% criteria for patients with sever 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: recieving 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
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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 shahriver 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
Street address
6th Km Gazvin- Rasht Road .Facuity of Medicine.Guilan University of Medical Sciences
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Person responsible for scientific inquiries

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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
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 Universityand the project supervisor

Comments