# 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 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**
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**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
**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 shahriver street
**City**
Rasht
**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

**Contact**

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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**