

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

30 May 2026

### A study on melatonin and Vitamin C and zinc efficacy in patients with COVID19 hospitalized in intensive care unit of Semnan Kowsar Hopsital

#### Protocol summary

##### Study aim

A study on melatonin and Vitamin C and zinc efficacy in patients with COVID19 hospitalized in intensive care unit of Semnan Kowsar Hopsital

##### Design

Clinical trial with control group, Randomized, Single-center, Sample size 30 people (2 groups of 15 people).

##### Settings and conduct

Kowsar Hospital in Semnan. In addition to national protocol medications, patients receive 40 mg of melatonin (2 5 mg tablets every 6 hours) via NG tube. Patients will also receive 2 grams of ascorbic acid per day at 5% dextrose every 6 hours, plus 220 mg of sulfate every 6 hours. The duration of treatment with this medication regimen will be 5 days.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with Covid 19; Conscious consent of the patient. Exclusion criteria: Malignant diseases; Severe renal, hepatic failure; History of drug allergy.

##### Intervention groups

Intervention group: In addition to national protocol medications, patients receive 40 mg of melatonin (2 5 mg tablets every 6 hours) via NG tube. Patients will also receive 2 grams of ascorbic acid per day at 5% dextrose every 6 hours, plus 220 mg of sulfate every 6 hours. The duration of treatment with this medication regimen will be 10 days. Control group: Patients are treated according to national protocol. Only for comparison with intervention group.

##### Main outcome variables

Number of breaths per minute; The rate of decline of lung infection; The course of the disease; Heart rate.

#### General information

##### Reason for update

Change the sample size from 20 to 30 people

##### Acronym

#### IRCT registration information

IRCT registration number: **IRCT20151228025732N52**

Registration date: **2020-04-09, 1399/01/21**

Registration timing: **registered\_while\_recruiting**

Last update: **2020-05-25, 1399/03/05**

Update count: **2**

#### Registration date

2020-04-09, 1399/01/21

#### Registrant information

##### Name

Alireza Emadi

##### Name of organization / entity

Semnan University of Medical Sciences, Semnan, Iran

##### Country

Iran (Islamic Republic of)

##### Phone

+98 23 3345 1336

##### Email address

are20935@semums.ac.ir

#### Recruitment status

**Recruitment complete**

#### Funding source

#### Expected recruitment start date

2020-04-07, 1399/01/19

#### Expected recruitment end date

2020-06-08, 1399/03/19

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

A study on melatonin and Vitamin C and zinc efficacy in patients with COVID19 hospitalized in intensive care unit of Semnan Kowsar Hopsital

## Public title

A study on melatonin and Vitamin C and zinc efficacy in patients with COVID19

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

Patients with Covid 19 Conscious consent of the patient

### Exclusion criteria:

Malignant diseases Severe renal, hepatic failure History of drug allergy

## Age

To 65 years old

## Gender

Both

## Phase

2

## Groups that have been masked

No information

## Sample size

Target sample size: 30

## Randomization (investigator's opinion)

Randomized

## Randomization description

Block randomization; Individual; Random Number Tables. Randomized permutation blocks (block 2). Using Excel software to generate random number tables

## Blinding (investigator's opinion)

Not blinded

## Blinding description

## Placebo

Not used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Semnan University of Medical Sciences

##### Street address

Semnan University of Medical Sciences, Basij Blvd, Semnan

##### City

Semnan

##### Province

Semnan

##### Postal code

3514799442

#### Approval date

2020-04-07, 1399/01/19

#### Ethics committee reference number

IR.SEMUMS.REC.1399.005

## Health conditions studied

### 1

#### Description of health condition studied

Covid-19

#### ICD-10 code

U07.01

#### ICD-10 code description

Covid-19 infection

## Primary outcomes

### 1

#### Description

Number of breaths per minute

#### Timepoint

Before the intervention, from the start of treatment to the patient's recovery

#### Method of measurement

Vital signs monitoring devices

### 2

#### Description

The rate of decline of lung infection

#### Timepoint

Before the intervention, from the start of treatment to the patient's recovery

#### Method of measurement

Clinical examination, if necessary, radiography or CT scan

### 3

#### Description

The course of the disease

#### Timepoint

Before the intervention, from the start of treatment to the patient's recovery

#### Method of measurement

Clinical examination, if necessary, radiography or CT scan

### 4

#### Description

Heart rate

#### Timepoint

Before the intervention, from the start of treatment to the patient's recovery

#### Method of measurement

Vital signs monitoring devices

## Secondary outcomes

empty

## Intervention groups

## 1

### Description

Intervention group: In addition to national protocol medications, patients receive 40 mg of melatonin (Simorgh Pharmaceutical Company); (2 tablets, 5 mg every 6 hours) via NG tube. Patients will also receive 2 grams of ascorbic acid per day at 5% dextrose(Daropaksh Company) every 6 hours, plus 220 mg of sulfate every 6 hours(Alhawi Company). The duration of treatment with this medication regimen will be 10 days.

### Category

Treatment - Drugs

## 2

### Description

Control group: Patients are treated according to national protocol. Only for comparison with intervention group.

### Category

Treatment - Other

## Recruitment centers

## 1

### Recruitment center

#### Name of recruitment center

Kowsar Hospital

#### Full name of responsible person

Mahboubeh Darban

#### Street address

Street Amin, Semnan

#### City

Semnan

#### Province

Semnan

#### Postal code

3519899951

#### Phone

+98 23 3345 1336

#### Email

are20935@gmail.com

## Sponsors / Funding sources

## 1

### Sponsor

#### Name of organization / entity

Semnan University of Medical Sciences

#### Full name of responsible person

Fatemeh Ehsani

#### Street address

Semnan University of Medical Sciences, Basij Blvd,  
Semnan.

#### City

Semnan

#### Province

Semnan

#### Postal code

3514799442

#### Phone

+98 23 3345 1336

#### Email

fatemehehsani59@yahoo.com

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Semnan 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

Semnan University of Medical Sciences

#### Full name of responsible person

Mahboubeh Darban

#### Position

Associate professor

#### Latest degree

Specialist

#### Other areas of specialty/work

Internal Medicine

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Semnan University of Medical Sciences, Basij Blvd,  
Semnan

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## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

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**Person responsible for updating data**

**Contact**

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**Sharing plan**

**Deidentified Individual Participant Data Set (IPD)**

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

**Study Protocol**

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

**Statistical Analysis Plan**

No - There is not a plan to make this available

**Informed Consent Form**

No - There is not a plan to make this available

**Clinical Study Report**

No - There is not a plan to make this available

**Analytic Code**

No - There is not a plan to make this available

**Data Dictionary**

No - There is not a plan to make this available