

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

Street address

Semnan University of Medical Sciences, Basij Blvd,
Semnan

City

Semnan

Province

Semnan

Postal code

3514799442

Phone

+98 23 3345 1336

Email

are20935@gmail.com

Person responsible for scientific 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

Street address

Semnan University of Medical Sciences, Basij Blvd,
Semnan

City

Semnan

Province

Semnan

Postal code

3514799442

Phone

+98 23 3345 1336

Email

are20935@gmail.com

Person responsible for updating data

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

Street address

Semnan University of Medical Sciences, Basij Blvd,
Semnan

City

Semnan

Province

Semnan

Postal code

3514799442

Phone

+98 23 3345 1336

Email

are20935@gmail.com

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