

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Jul 2026

Effect of melatonin versus placebo on serum levels of oxidative stress biomarkers and clinical outcomes in patients with septic shock: a double-blind randomized clinical trial

Protocol summary

Study aim

To assess the effect of melatonin versus placebo on serum levels of oxidative stress biomarkers and clinical outcomes in patients with septic shock

Design

This is a double-blind randomized clinical trial, phase II, in which 40 eligible patients will be randomly assigned to the intervention and control groups

Settings and conduct

The eligible patients with septic shock who will refer to Besat Hospital in Hamadan City during the study period will be enrolled in the trial and will be randomly assigned to the intervention and control groups through the block randomization. This trial will be double-blinded so that neither patients nor the physician who will examine the patients will be aware of the intervention.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age of 18 to 65 years, Septic shock,
Exclusion criteria: Pregnancy or breastfeeding,
Contraindication of intestinal nutrition, Using other antioxidants or anti-inflammatory drugs, Liver or renal chronic diseases

Intervention groups

Intervention group: Routine treatment plus oral melatonin 50 mg made by Sepidteb Pharmaceutical Factory daily for 5 days through a nasogastric tube
Control group: Routine treatment plus oral placebo made by the laboratory of the Hamadan School of Pharmacy daily for 5 days through a nasogastric tube

Main outcome variables

Primary outcome: Catalase activity, Superoxide dismutase activity, Glutathione peroxidase activity, Malondialdehyde activity, The occurrence of death, Duration of mechanical ventilation, Duration of hospitalization, The average dose of vasopressor

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120215009014N296**

Registration date: **2019-09-15, 1398/06/24**

Registration timing: **prospective**

Last update: **2019-09-15, 1398/06/24**

Update count: **0**

Registration date

2019-09-15, 1398/06/24

Registrant information

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Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-09-23, 1398/07/01

Expected recruitment end date

2020-09-22, 1399/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of melatonin versus placebo on serum levels of oxidative stress biomarkers and clinical outcomes in patients with septic shock: a double-blind randomized clinical trial

Public title

Effect of melatonin versus placebo on serum levels of oxidative stress biomarkers and clinical outcomes in patients with septic shock

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Age of 18 to 65 years Septic shock

Exclusion criteria:

Pregnancy or breastfeeding Contraindication of intestinal nutrition Using other antioxidants or anti-inflammatory drugs Liver or renal chronic diseases

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

2

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

The patients will be randomly assigned to intervention and control groups using block randomization. For this purpose, we will prepare four sheets of paper, writing on two sheets the name of the intervention and on the other two sheets the name of the control. The paper sheets will be pooled, placed in a container, and randomly drawn one at a time for each patient without replacement until all four sheets are drawn. The four paper sheets will be then placed back into the container, and this action repeated until the sample size is reached.

Blinding (investigator's opinion)

Double blinded

Blinding description

The shape of the medications and placebos will be perfectly the same. Therefore, patients will be unaware of the type of intervention. The physician who will examine the patients will not be aware of the intervention. Thus, the trial will be run as double-blind

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics Committee of Hamadan University of Medical Sciences

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Vice-chancellor for Research and Technology,
Hamadan University of Medical Sciences, Shahid
Fahmideh Ave

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Province

Hamadan

Postal code

6517838695

Approval date

2019-07-21, 1398/04/30

Ethics committee reference number

IR.UMSHA.REC.1398.341

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

Septic shock

ICD-10 code

R65.21

ICD-10 code description

Severe sepsis with septic shock

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

Catalase activity

Timepoint

Before the intervention and on the second, third, fourth
and fifth days after the intervention

Method of measurement

Using laboratory Kit special for catalase

2**Description**

Superoxide dismutase activity

Timepoint

Before the intervention and on the second, third, fourth
and fifth days after the intervention

Method of measurement

Using laboratory Kit special for superoxide dismutase

3

Description

Glutathione peroxidase activity

Timepoint

Before the intervention and on the second, third, fourth and fifth days after the intervention

Method of measurement

Using laboratory Kit special for glutathione peroxidase

4

Description

Malondialdehyde activity

Timepoint

Before the intervention and on the second, third, fourth and fifth days after the intervention

Method of measurement

Using laboratory Kit special for malondialdehyde

5

Description

Occurrence of death

Timepoint

Up to the fifth day after the intervention

Method of measurement

By clinical observation

6

Description

Duration of mechanical ventilation

Timepoint

Up to the fifth day after the intervention

Method of measurement

By clinical observation

7

Description

Duration of hospitalization

Timepoint

Up to the fifth day after the intervention

Method of measurement

By clinical observation

8

Description

Average dose of vasopressor

Timepoint

Up to the fifth day after the intervention

Method of measurement

By clinical observation

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Routine treatment plus oral melatonin 50 mg made by Sepidteb Pharmaceutical Factory daily for 5 days through a nasogastric tube

Category

Treatment - Drugs

2

Description

Control group: Routine treatment plus oral placebo made by the laboratory of the Hamadan School of Pharmacy daily for 5 days through a nasogastric tube

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Besat Hospital in Hamadan City

Full name of responsible person

Farnaz Shkouhmand

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Hamedan 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

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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

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

Undecided - It is not yet known if there will be 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

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