Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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

Name

Jalal Poorolajal

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
Street address
Vice-chancellor for Research and Technology, Hamadan University of Medical Sciences, Shahid Fahmideh Ave
City
Hamadan
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
Occurence 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
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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
Name of organization / entity
Hamedan University of Medical Sciences
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Anesthesiologist
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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