Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Sep 2026

Evaluation of the effect of melatonin on inflammatory factors and clinical outcomes in sepsis patients hospitalized in the Intensive Care Unit

Protocol summary

Study aim
Determining the effectiveness of melatonin on inflammatory cytokines and clinical outcomes of sepsis patients admitted to the ICU

Design
A double-blind, randomized, phase 3 controlled clinical trial with a parallel group design on 60 patients. The randbetween function in Excel will be used to select the blocks randomly.

Settings and conduct
The current study is a double-blind, randomized clinical trial with two intervention and control arms, which will investigate the effect of melatonin administration as an adjunctive treatment in sepsis patients hospitalized in the ICU of Imam Khomeini Hospital, Sari.

Participants/Inclusion and exclusion criteria
Patients with the early phase of sepsis, Age over 18 years, not receiving antioxidant supplements, informed consent of the patient or his legal guardian to participate in the study. Exclusion criteria: autoimmune diseases or cancer, septic shock and the need for inotropic or vasopressor drugs, hepatic or renal failure, intestinal obstruction, ileus, gastroparesis or other digestive conditions that can affect intestinal absorption. Pregnancy and breastfeeding, history of sleep disorders, simultaneous presence in another study

Intervention groups
The intervention group: melatonin at a dose of 15 mg every night, The control group will receive a placebo for the first 7 days of hospitalization in ICU

Main outcome variables
The IL-6 level, The IL-10 level, Total antioxidant capacity, The number and types of WBCs, CRP, and procalcitonin, The hospitalization duration, Mortality rate, Duration of ventilation and need for ventilation, The SOFA score, The GCS score,

General information

Reason for update
Updating the process of entering patients into the study

Acronym

IRCT registration information
IRCT registration number: **IRCT20181104041551N4**
Registration date: **2024-02-01, 1402/11/12**
Registration timing: **prospective**

Last update: **2024-02-19, 1402/11/30**
Update count: **1**

Registration date
2024-02-01, 1402/11/12

Registrant information

Name
Fateme Heydari

Name of organization / entity

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2024-02-09, 1402/11/20

Expected recruitment end date
2024-05-21, 1403/03/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluation of the effect of melatonin on inflammatory factors and clinical outcomes in sepsis patients hospitalized in the Intensive Care Unit

Public title
Evaluation of the effect of melatonin on inflammatory factors and clinical outcomes in sepsis

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Patients with early phase of sepsis Not taking antioxidant supplements Informed consent of the patient or his/her legal guardian to participate in the study

Exclusion criteria:
Autoimmune diseases or cancer Septic shock that requires inotrope or vasopressor drugs Hepatic failure Renal failure requiring dialysis Intestinal obstruction, ileus, gastroparesis, or other gastrointestinal conditions that can affect intestinal absorption Pregnancy and breastfeeding History of sleep disorders Attending another study at the same time

Age
From **18 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size
Target sample size: **56**

Randomization (investigator's opinion)
Randomized

Randomization description
Blocked random allocation method will be used to randomly assign the patients to two intervention groups and the control group. For this purpose, the "randbetween" formula will be used in Excel software. The generated numbers will be between 1 and 6. Then, based on the generated number, samples will be assigned to the intervention and control groups.

Blinding (investigator's opinion)
Triple blinded

Blinding description
Melatonin and placebo medicine will be placed in separate packages. Only the main operator of the study will know how to assign the codes. The patient, the anesthesiologist (data collector) and the statistical evaluator will be blind in this study. At the end of the study, the codes will be broken for statistical analysis.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Research Ethics Committee, Imam Hospital of Sari, Mazandaran University of Medical Sciences

Street address
Imam Hospital, Amir Mzandarani Blvd.

City
Sari

Province
Mazandaran

Postal code
5714854367

Approval date
2023-08-14, 1402/05/23

Ethics committee reference number
IR.MAZUMS.IMAMHOSPITAL.REC.1402.084

Health conditions studied

1

Description of health condition studied
sepsis

ICD-10 code
A41

ICD-10 code description
Other sepsis

Primary outcomes

1

Description
The interleukin-6 level

Timepoint
At baseline and 7 days after (the end of study)

Method of measurement
Elysia kit

2

Description
The interleukin-10 level

Timepoint
At baseline and 7 days after (the end of study)

Method of measurement
Elysia kit

3

Description
WBC (diff), CRP and PCT

Timepoint
At baseline and 7 days after (the end of study)

Method of measurement
Laboratory report

4

Description
Total antioxidant capacity
Timepoint
At baseline and 7 days after (the end of study)
Method of measurement
Elysia kit

5

Description
SOFA score
Timepoint
At baseline and 7 days after (the end of study)
Method of measurement
Laboratory and clinical findings

Secondary outcomes

1

Description
Comparison of the effect of melatonin with placebo on the GCS in sepsis patients
Timepoint
Daily
Method of measurement
Clinical observation

2

Description
Comparison of the effect of melatonin with placebo on the need for ventilation and duration of ventilation in sepsis patients
Timepoint
Dialy
Method of measurement
Clinical observation

3

Description
Comparison of the effect of melatonin with placebo on the mortality rate of sepsis patients
Timepoint
Daily
Method of measurement
Clinical observation

Intervention groups

1

Description
Intervention group: Melatonin with a dose of 15 mg per day. It should be noted that the routine treatment of patients (such as receiving antibiotics, conventional supportive treatments, etc.) will not change during the intervention period. Entering this study will not lead to a change in the patient's routine treatment process. The duration of the intervention will be 7 days.
Category
Treatment - Drugs

2

Description
Control group: They will receive a pill that is similar in appearance and color to the intervention group but contains starch or lactulose.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Khomeini Educational Hospital, Sari
Full name of responsible person
Fatemeh Heidari
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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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Email
pajhooheshi@mazums.ac.ir
Web page address
https://research.mazums.ac.ir/?AspxAutoDetectCookieSupport=1
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Mazandaran 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
Mazandaran University of Medical Sciences
Full name of responsible person
Dr. Fatemeh Heydari
Position
Assistant professor
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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
Not applicable
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Not applicable
Data Dictionary
Not applicable
Title and more details about the data/document
Files related to the results of laboratory tests and statistical analyses
When the data will become available and for how

long

After completing the study and publishing the article

To whom data/document is available

Researchers working in academic and scientific institutions

Under which criteria data/document could be used

Only statistical analyzes are allowed for use in review articles

From where data/document is obtainable

Dr Fatemeh Heydari

What processes are involved for a request to access data/document

Sending an email to Dr Fatemeh Heydari - checking the request - if approved, sending it to the requester

Comments