

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)

Phone

+98 11 3336 1700

Email address

f.heydari@mazums.ac.ir

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

Daily

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

Street address

Imam Khomeini Educational Hospital, Razi St.

City

Sari

Province

Mazandaran

Postal code

4816633131

Phone

+98 11 3336 1700

Email

fateme58@yahoo.com

Web page address

<http://imamhospital.mazums.ac.ir/>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Dr Pedram Ebrahimnezhad

Street address

Moalem Square - Vice President of Research of Mazandaran University of Medical Sciences

City

Sari

Province

Mazandaran

Postal code

۴۸۱۵۷۳۳۹۷۱

Phone

+98 11 3325 7230

Fax

+98 11 3326 1244

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

Latest degree

Subspecialist

Other areas of specialty/work

Anesthesiology

Street address

Imam Hospital, Amir Mazandarani Blvd.

City

Sari

Province

Mazandaran

Postal code

5714854397

Phone

+98 11 3335 0672

Email

f.heydari@mazums.ac.ir

Person responsible for scientific inquiries**Contact****Name of organization / entity**

Mazandaran University of Medical Sciences

Full name of responsible person

Dr Fatemeh Heydari

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

Anesthesiology

Street address

Sari-Amir Mazandarani Boulevard- Imam Khomeini Hospital

City

Sari

Province

Mazandaran

Postal code

4816633131

Phone

+98 11 3335 0670

Email

fateme58@yahoo.com

Person responsible for updating data**Contact****Name of organization / entity**

Mazandaran University of Medical Sciences

Full name of responsible person

Dr Fatemeh Heydari

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

Anesthesiology

Street address

Imam Khomeini Hospital-Amir Mazandarani Boulevard

City

Sari

Province

Mazandaran

Postal code

4816633131

Phone

+98 11 3335 0670

Email

fateme58@yahoo.com

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