

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

Evaluating the effect of oral melatonin in colistin induced nephrotoxicity in the intensive care unit

Protocol summary

Study aim

Melatonin effect on colistin Nephrotoxicity

Design

Clinical trial with control group, with parallel groups, double-blind, randomized, 40 patients. Excel software rand function was used for randomization.

Settings and conduct

All patients admitted to the intensive care unit receiving colistin who have given informed consent and have not died prematurely in less than 72 hours, whose serum creatinine level at the onset of colistin should not be greater than 1.5 mg/dl And the intervention group received melatonin tablets made by nature made company with a dose of three mg per day and in the control group, the corresponding placebo in the same form. Patients are monitored daily for urine volume and blood levels of creatinine and urea until they receive cleistine, and will be assessed by AKIN and RIFLE criteria. To identify patients, the APACHEII score and the reason for admission to the patients 'ICU will be recorded upon arrival. Patients' demographic criteria will be recorded.

Participants/Inclusion and exclusion criteria

Admission requirements include all patients admitted to the General ICU who are being treated for Colistin Non-entry conditions include dissatisfaction of the patient or legal guardian and patients with renal insufficiency and increased serum creatinine

Intervention groups

The intervention group of melatonin tablets made by nature made company with a dose of three mg per day through the gastric tube and in the control group, receive the corresponding placebo with the same dose. Patients are monitored daily for urine volume and blood levels of creatinine and urea until they receive colistin, and will be assessed by Acute kidney Injury Network (AKIN) and Risk, injury, Failure, loss, End stage (RIFLE) criteria.

Main outcome variables

Urine volume, which is measured daily in the ward, and

serum creatinine level, which is measured daily by the hospital laboratory

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210110049990N1**

Registration date: **2021-03-01, 1399/12/11**

Registration timing: **prospective**

Last update: **2021-03-01, 1399/12/11**

Update count: **0**

Registration date

2021-03-01, 1399/12/11

Registrant information

Name

seyedpouzhia shojaei

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

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Email address

p.shojaei@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-03-21, 1400/01/01

Expected recruitment end date

2021-09-22, 1400/06/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluating the effect of oral melatonin in colistin induced nephrotoxicity in the intensive care unit

Public title

Evaluation of the effect of melatonin on colistin nephrotoxicity

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

All patients that admitted to the intensive care unit who are being treated with Colistin

Exclusion criteria:

Patient or legal counsel dissatisfaction
People under 18 years old
People with impaired kidney function and creatinine levels greater than 1.5 mg / dL

Age

From **18 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Care provider

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Using statistical software tools randomized using random numbers to assign a code to each patient by the pharmacotrapist is done with the conceal. The distribution of melatonin to the intervention group and placebo to the control group is done by the ward nurses based on the accident reported by the pharmacotherapist. Researchers and nurses will not be aware of the results of randomization and the type of package they give to patients. The researcher provides the necessary medication for the nurses to perform the intervention.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this double-blind study, the pharmacotherapist performs randomized statistical software using randomized statistical software. The drug and placebo are given a code and key about the drugs is given only to the principal investigator.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethic committee of Shahid Beheshti University of Medical Science

Street address

Imam Hossein Hospital, Madani Ave, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1476716165

Approval date

2020-12-29, 1399/10/09

Ethics committee reference number

IR.SBMU.MSP.REC.1399.581

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

Nephrotoxicity

ICD-10 code

N17.9

ICD-10 code description

Acute kidney failure, unspecified

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

24-hour urine volume

Timepoint

Ten days

Method of measurement

Container for measuring the volume of liquids

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: Patients receive a treatment protocol approved by the Ministry of Health during their hospital stay. Patients in the intensive care unit treated with colistin will receive one melatonin tablet at a dose of 3 mg per night. Melatonin is a substance that is naturally secreted through the pineal gland and its role is to help

the sleep-wake cycle.

Category

Treatment - Drugs

2

Description

Control group: Patients receive a treatment protocol approved by the Ministry of Health during their hospital stay. They will receive a placebo every night for a maximum of ten nights.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Hossein Hospital

Full name of responsible person

Poujea Shojaei

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University Of Medical Science

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?

No

Title of funding source

Shahid Beheshti 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

2

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

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?

No

Title of funding source

Vice-Chancellor for Research of shahid Beheshti University

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

Shahid Beheshti University of Medical Sciences
Full name of responsible person
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Position
Assist Professor
Latest degree
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Person responsible for updating data

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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

Yes - There is a plan to make this available

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

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

In this study, none of the patients' personal information will be shared. Only data that is shared relates to the main consequences of the intervention.

When the data will become available and for how long

The access period starts 6 months after the results are published.

To whom data/document is available

The data will be available to researchers at academic and scientific institutions as well as physicians.

Under which criteria data/document could be used

Applicants are only allowed to use the information available to them only in clinical practice and should not publish this information.

From where data/document is obtainable

Ways of contacting applicants: 1- Contact number: 09181110628 2- E-mail address: p.Shojaei @ sbmu.ac.ir 3- Address: Tehran, Shahid Madani St., Imam Hossein Hospital, Dr. Pouja Shojaei

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

Applicants should receive the necessary information within ten days after making a call to the announced numbers or sending an email.

Comments