Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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 grater 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)
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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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Imam Hossein Hospital,Madani Ave, Tehran, Iran

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http://www.ehmc.ir/

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University Of Medical Science

Full name of responsible person

Afshin Zarghi

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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
Poujea Shojaei

Position
Assist Professor

Latest degree
Subspecialist

Other areas of specialty/work
Anesthesiology

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Person responsible for updating data

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Web page address

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