

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

03 Jun 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

+98 21 7343 0000

##### 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

**Street address**

Imam Hossein Hospital, Madani Ave, Tehran, Iran

**City**

Tehran

**Province**

Tehran

**Postal code**

1476716165

**Phone**

+98 21 7343 0000

**Email**

mohammadtorabi628@yahoo.com

**Web page address**

<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

**Street address**

SBUMS, Arabi Ave, Daneshjoo Blvd, Velenjak, Tehran, Iran

**City**

Tehran

**Province**

Tehran

**Postal code**

1476716165

**Phone**

+98 21 7343 0000

**Email**

P.Shojaei @sbmu.ac.ir

**Web page address**

<http://www.ehmc.ir/>

**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**

پوزیا شجاعی

**Street address**

Imam Hossein Hospital, Madani Ave. Tehran, Iran

**City**

Tehran

**Province**

Tehran

**Postal code**

1476716165

**Phone**

+98 21 7343 0000

**Email**

Mohammadtorabi628@yahoo.com

**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  
**Street address**  
Imam Hossein Hospital, Madani Ave, Tehran, Iran  
**City**  
Tehran  
**Province**  
Tehran  
**Postal code**  
1476716165  
**Phone**  
+98 21 7343 0000  
**Email**  
mohammadtorabi628@yahoo.com

## Person responsible for scientific 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  
**Street address**  
Imam Hossein Hospital, Madani Ave, Tehran, Iran  
**City**  
Tehran  
**Province**  
Tehran  
**Postal code**  
1476716165  
**Phone**  
002173430000  
**Email**  
mohammadtorabi628@yahoo.com

## Person responsible for updating data

### Contact

**Name of organization / entity**  
Shahid Beheshti University of Medical Sciences  
**Full name of responsible person**  
Poujia Shojaei  
**Position**  
Assist Professor  
**Latest degree**

Subspecialist  
**Other areas of specialty/work**  
Anesthesiology  
**Street address**  
Imam Hossein Hospital, Madani Ave, Tehran, Iran  
**City**  
Tehran  
**Province**  
Tehran  
**Postal code**  
1476716165  
**Phone**  
+98 21 7343 0000  
**Email**  
Mohammadtorabi628@yahoo.com  
**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