

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Evaluation the effect of melatonin in prevention of vancomycin induced nephrotoxicity in critically ill patients: A randomized controlled clinical trial

Protocol summary

Study aim

Evaluation of the melatonin role on vancomycin-induced acute nephrotoxicity in critically ill patients

Design

Randomized, double blinded, placebo controlled clinical trial was conducted among 41 patients (20 patients in melatonin group and 21 patients in control group).

Random number table was used for randomization.

Settings and conduct

This randomized, clinical trial is performed in intensive care unit (ICU) of Al-Zahra hospital, Isfahan. This study was designed to evaluate the effect of oral melatonin (3 mg tablet twice daily for 7 days) and comparison with placebo, in the prevention of vancomycin-induced acute renal injury, according to serum Neutrophil gelatinase-associated lipocalin (NGAL) and creatinine level changes. This is a double blinded study, that means participants, and the assessors of the outcomes are unaware of the study group, and moreover seemingly identical medications was used in melatonin and placebo groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Adult patients who received intravenous vancomycin, creatinine clearance ≥ 45 milliliter per minute at study recruitment, and oral tolerance to the drug. Exclusion criteria: Receiving intravenous vancomycin or melatonin for at least 2 weeks before study recruitment, acute kidney injury before study recruitment

Intervention groups

Melatonin group: Administration of 3 mg melatonin tablet twice daily for 7 days Placebo group: Administration of placebo tablet twice daily for 7 days

Main outcome variables

Serum level of Neutrophil gelatinase-associated lipocalin, serum creatinine level

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150221021159N4**

Registration date: **2020-06-27, 1399/04/07**

Registration timing: **retrospective**

Last update: **2020-06-27, 1399/04/07**

Update count: **0**

Registration date

2020-06-27, 1399/04/07

Registrant information

Name

Shadi Farsaei

Name of organization / entity

Isfahan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 31 3792 2618

Email address

farsaei@pharm.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-07-23, 1397/05/01

Expected recruitment end date

2019-07-23, 1398/05/01

Actual recruitment start date

2018-10-23, 1397/08/01

Actual recruitment end date

2019-07-23, 1398/05/01

Trial completion date

2019-09-23, 1398/07/01

Scientific title

Evaluation the effect of melatonin in prevention of vancomycin induced nephrotoxicity in critically ill patients: A randomized controlled clinical trial

Public title

valuation the effect of melatonin in prevention of vancomycin induced nephrotoxicity

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Adult patients who received intravenous vancomycin. Creatinine clearance more than 45 milliliter per minute at study recruitment Oral tolerance to the drug

Exclusion criteria:

Receiving intravenous vancomycin or melatonin for at least 2 weeks before study recruitment Acute kidney injury before study recruitment

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size

Target sample size: **40**

Actual sample size reached: **41**

Randomization (investigator's opinion)

Randomized

Randomization description

The pockets containing medications (melatonin and placebo) were coded, and each code was written on the specific card. Thereafter, eligible patient was assigned to each group, randomly by selecting among shuffling cards. So, allocation sequence was concealed until the moment of assignment, and nobody knows what is the next treatment allocation must be. It should be mentioned that participants, health care providers, assessor and data collector unaware of the assigned intervention (allocated codes).

Blinding (investigator's opinion)

Double blinded

Blinding description

Seemingly identical medications were used in placebo and melatonin group. Moreover, participants, health care providers, assessor and data collector unaware of allocated code in each study group.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Isfahan University of Medical sciences

Street address

Bldg No. 4, Isfahan University of Medical Sciences and Health Services, Hizar jarib street

City

Isfahan

Province

Isfahan

Postal code

8174673461

Approval date

2018-10-25, 1397/08/03

Ethics committee reference number

IR.MUI.REC.1395.3.861

Health conditions studied

1

Description of health condition studied

Acute kidney failure

ICD-10 code

N17.9

ICD-10 code description

Acute kidney failure, unspecified

Primary outcomes

1

Description

Acute kidney failure based on changes of serum neutrophil gelatinase-associated lipocalin (NGAL) levels.

Timepoint

At the initial of study (before initiation of colistin) and 7 days after intervention.

Method of measurement

ELISA Kit

2

Description

Acute kidney failure based on changes of serum creatinine levels.

Timepoint

At the initial of study (before initiation of colistin) and 7 days after

Method of measurement

Creatinine assay kit

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Melatonin tablets made in nature made company are administered orally at the dose of 3 mg twice daily for 7 days, on the same date of starting colistin

Category

Prevention

2

Description

Control group: Placebo tablets made at the faculty of pharmacy with the same appearance as melatonin tablet are prescribed twice daily, for 7 days

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

AlZahra hospital

Full name of responsible person

Shadi Farsaei

Street address

No.53, 29th Alley , Chahar Bagh Paen Ave., Isfahn, Iran

City

Isfahan

Province

Isfahan

Postal code

8148614481

Phone

+98 31 3792 7071

Email

farsaei@pharm.mui.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Shaghayegh haghjou Javanmard

Street address

Gostaresh Bldg No. 4, Isfahan University of Medical Sciences and Health Services, Hezarjerib Ave., Isfahan, Iran.

City

Isfahan

Province

Isfahan

Postal code

8174673461

Phone

+98 31 3668 8138

Email

research@mui.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Esfahan 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

Esfahan University of Medical Sciences

Full name of responsible person

Shadi Farsaei

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Medical Pharmacy

Street address

Clinical pharmacy and pharmaceutical practices department, Pharmacy faculty, Isfahan university of medical sciences, Hezarjerib St.

City

Isfahan

Province

Isfahan

Postal code

8174673461

Phone

+98 31 3792 7071

Email

Farsaei@pharm.mui.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Shadi Farsaei

Position

Associate professor

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

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

Esfahan University of Medical Sciences

Full name of responsible person

Shadi Farsaei

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Medical Pharmacy

Street address