Clinical Trial Protocol
Iranian Registry of Clinical Trials

13 Nov 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 metalonin (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 gelatinasee-associated lipocalin, serum creatinin 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

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Isfahan University of Medical Sciences
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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

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Province
Isfehan

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
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
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Full name of responsible person
Shadi Farsaei
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Associate professor
Latest degree
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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