Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Evaluation of The Effect of N-acetylcysteine in The Prevention of Vancomycin-Induced Nephrotoxicity

Protocol summary

Study aim
Recommendation for Use of Acetylcysteine in Patients Receiving Vancomycin, If Positive Results Were Observed

Design
Randomized, Parallel Group, Controlled Clinical Trial

Settings and conduct
This study was performed in Al-Zahra hospital affiliated to Isfahan University of Medical Sciences. Patients who received vancomycin for any indication and met the inclusion criteria, were randomly assigned to two groups of drug (NAC) and control. Vancomycin was initially administered at 15 mg/kg IV every 12 hours followed by dose adjustment to obtain a trough concentration of 10 – 15 mg/L. The patients in drug group received oral NAC 600 mg twice daily for 10 days started concurrently with vancomycin, while the patients in control group received vancomycin alone. Serum level of creatinine (SCr) and blood urea nitrogen (BUN) as well as creatinine clearance (CrCl) and 12-hour urine volume were recorded before the start of interventions, every other day during the study, and 12 hours after the last dose of vancomycin in 10th day of therapy for all patients.

Participants/Inclusion and exclusion criteria
age > 18 years; receiving vancomycin for at least 5 days; creatinine clearance > 60 ml/min; not having proteinuria and/or hematuria; not having any renal disorder; not using any other nephrotoxic drug

Intervention groups
Drug Group: Taking N-acetylcysteine 600 mg Twice Daily with Vancomycin Control Group: Taking Vancomycin alone

Main outcome variables
Serum Creatinine; Blood Urea Nitrogen; Creatinine Clearance; 12-hour Urine Output; The Number of Cases of Acute Kidney Injury

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20150721023282N3**
Registration date: **2019-02-19, 1397/11/30**
Registration timing: **retrospective**

Last update: **2019-02-19, 1397/11/30**
Update count: **0**

Registration date
2019-02-19, 1397/11/30

Registrant information

Name
Rasool Soltani

Name of organization / entity
Isfahan University of Medical Sciences

Country
Iran (Islamic Republic of)

Phone
+98 31 3792 7067

Email address
soltani@pharm.mui.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2017-09-23, 1396/07/01

Expected recruitment end date
2018-03-20, 1396/12/29

Actual recruitment start date
2017-09-23, 1396/07/01

Actual recruitment end date
2018-03-20, 1396/12/29

Trial completion date
2018-03-20, 1396/12/29

Scientific title
Evaluation of The Effect of N-acetylcysteine in The Prevention of Vancomycin-Induced Nephrotoxicity

Public title
Evaluation of The Effect of N-acetylcysteine in The Prevention of Vancomycin-Induced Renal Disorder
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Treatment with Vancomycin for at Least 5 Days
Creatinine Clearance > 60 ml/min (Based on MDRD Formula)
Exclusion criteria:
Age
From **18 years** old
Gender
Both

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **80**
Actual sample size reached: **179**
Randomization (investigator's opinion)
Randomized
Randomization description
Simple Randomization Individual Random Number Table Even Numbers: Drug Group; Odd Numbers: Control Group
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethical Committee of Isfahan University of Medical Sciences
Street address
Isfahan University of Medical Sciences, Hezar-Jerib Ave.
City
Isfahan
Province
Isfehan
Postal code
8174673461
Approval date
2015-05-28, 1394/03/07
Ethics committee reference number
294065

Health conditions studied

1

Description of health condition studied
Vancomycin-Induced Nephrotoxicity
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Serum Creatinine
Timepoint
At baseline and 2, 4, 6, 8, and 10 days after initiation of intervention
Method of measurement
Spectrophotometry

2

Description
Blood Urea Nitrogen
Timepoint
At baseline and 2, 4, 6, 8, and 10 days after initiation of intervention
Method of measurement
Spectrophotometry

3

Description
Creatinine Clearance
Timepoint
At baseline and 2, 4, 6, 8, and 10 days after initiation of intervention
Method of measurement
Cockroft - Gault Formula

4

Description
12-hour Urine Volume
Timepoint
At baseline and 2, 4, 6, 8, and 10 days after initiation of intervention
Method of measurement
Urine Bag

5

Description
The number of patients with acute kidney injury
Timepoint
End of intervention
Method of measurement
counting

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: N-acetylcysteine, 600 mg, twice daily, for 10 days
Category
Prevention

2

Description
Control group: Without intervention
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Al-Zahra Hospital
Full name of responsible person
Rasool Soltani
Street address
Soffeh Ave.
City
Esfahan
Province
Isfehan
Postal code
8174675731
Phone
+98 31 3620 2020
Email
soltani@pharm.mui.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Vice-Chancellor for Research
Street address
Hezar-Jerib Ave.
City
Esfahan
Province
Isfehan
Postal code
81746-83461
Phone
+98 31 3668 0048
Email
soltani@pharm.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
Rasool Soltani
Position
Associate professor
Latest degree
Specialist
Other areas of specialty/work
Medical Pharmacy
Street address
No. 20, Bagh Daryacheh Ave.
City
Esfahan
Province
Isfehan
Postal code
8176776161
Phone
+98 31 3786 5537
Email
soltani@pharm.mui.ac.ir

Person responsible for scientific inquiries

Contact
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Rasool Soltani
Position
Associate professor
Latest degree
Specialist
Other areas of specialty/work
Medical Pharmacy
Street address

No. 20, Bagh Daryacheh Ave.
City
Isfahan
Province
Isfehan
Postal code
8176776161
Phone
+98 31 3786 5537
Fax
+98 31 3668 0011
Email
soltani@pharm.mui.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Rasool Soltani
Position
Associate professor
Latest degree
Specialist
Other areas of specialty/work
Medical Pharmacy
Street address
No. 20, Bagh Daryacheh Ave.
City
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Province
Isfehan
Postal code
8176776161
Phone
+98 31 3786 5537
Email
soltani@pharm.mui.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
More data is not present.
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available