

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jul 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

Isfahan

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

Cockcroft - 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

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Soffeh Ave.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Vice-Chancellor for Research

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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

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

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Person responsible for scientific inquiries

Contact

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Full name of responsible person

Rasool Soltani

Position

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Latest degree

Specialist

Other areas of specialty/work

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Person responsible for updating data

Contact

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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