Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Jul 2026

Evaluation of the effectiveness of N-acetylcysteine in the prevention of colistin-induced nephrotoxicity: a randomized controlled clinical trial

Protocol summary

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

Design
Randomized Controlled Clinical Trial

Settings and conduct
This study is performed in Alzahra hospital affiliated to Isfahan University of Medical Sciences. Patients who received colistin for a standard dose of 4.5 million units of sodium colistemate every 12 hours for any reason and met the inclusion criteria were randomly divided into two groups (n-acetylcysteine) and control. Patients in the drug group received 600 mg of N-acetylcysteine twice daily for 10 days, starting with colistin, whereas patients in the control group received colistin only. Serum level of creatinine (SCr) and blood urea nitrogen (BUN) as well as creatinine clearance (CrCl) will be 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, as well as serum NGAL levels before the intervention and 5 days after the intervention (Before administration of colistin) will be recorded for all patients. Finally, by means of statistical tests, mean serum creatinine, BUN, CrCl and NGAL measured at time points and the incidence of acute renal injury will be compared between the NAC and control groups according to the number of cases per stage.

Participants/Inclusion and exclusion criteria
50>age > 18 years; receiving Clistin at 4.5 million units every 12 hours; creatinine clearance > 90 ml/min; not having proteinuria and/or hematuria; not having any renal disorder; not using any other nephrotoxic drug; No history of NAC allergy

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

Main outcome variables
Serum Creatinine; Blood Urea Nitrogen; Creatinine Clearance; Serum Level Of NGAL; The Number of Cases of Acute Kidney Injury

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20150721023282N6**
Registration date: **2019-12-19, 1398/09/28**
Registration timing: **registered_while_recruiting**

Last update: **2019-12-19, 1398/09/28**
Update count: **0**

Registration date
2019-12-19, 1398/09/28

Registrant information

Name
Rasool Soltani
Name of organization / entity
Isfahan University of Medical Sciences
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Iran (Islamic Republic of)
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-09-22, 1398/06/31

Expected recruitment end date
2020-03-18, 1398/12/28

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluation of the effectiveness of N-acetylcysteine in the prevention of colistin-induced nephrotoxicity: a randomized controlled clinical trial

Public title
Evaluation of The Effect of N-acetylcysteine in The Prevention of Vancomycin-Induced Renal Disorder

Purpose
Prevention

Inclusion/Exclusion criteria
Inclusion criteria:
Take colistin at a dose of 4.5 million units every 12 hours Creatinine Clearance > 90 ml/min (Based on CKD-EPI Formula)
Exclusion criteria:
Underlying kidney disorder Receiving other nephrotoxic drugs

Age
From **18 years** old to **50 years** old

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
Block randomization: Blocks of 4 will be used and patients will be assigned to drug and control groups based on the determined sequences in the blocks.

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
2019-08-03, 1398/05/12

Ethics committee reference number
IR.MUI.RESEARCH.REC.1398.361

Health conditions studied

1

Description of health condition studied

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
CKD-EPI Formula

4

Description
NGAL serum level

Timepoint
At baseline and 5 days after initiation of intervention

Method of measurement
NGAL Measurement Kit

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, PO

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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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Shaghayegh Haghjooy Javanmard

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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

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Person responsible for updating data

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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