

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 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 colistinate 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

Country

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.

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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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

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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

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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