Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Evaluation of Effect of N-acetylcysteine On Rate and Severity of Colistin Nephrotoxicity: A Randomized Double-blind Placebo-controlled Trial

Protocol summary

Study aim

Evaluation of the effect of N-acetylcysteine on the extent and severity of colistin-induced nephrotoxicity

Design

Clinical trial with two parallel groups, with a control group, placebo, double-blind, phase 3, sample size of 48 people. Randomization with the help of Excel software and quadruple blocks

Settings and conduct

This study is done in order to investigate the effect of N-acetyl cysteine on the rate and severity of colistin-induced nephrotoxicity in patients with nosocomial infection admitted to intensive care unit (ICU) and normal care departments in Fatemeh Zahra Hospital, Sari. This study has two arms of medicine and placebo, and a four-digit code is assigned to each patient through the Excel program. In this study, the doctor, clinical assessor and patient will not know about the drug used (placebo or N-acetylcysteine).

Participants/Inclusion and exclusion criteria

Patients with nosocomial infections who are candidates to receive injectable colistin for 5 days or more, over 18 years of age are included in the study. Dialysis patients, glomerular filtration less than 60 ml/min, systolic blood pressure less than 90 mmHg, pregnant and lactating women, and cases with sensitivity to N-acetylcysteine or colistin are not included in the study.

Intervention groups

Intervention group: injectable N-acetylcysteine 2 grams daily along with starting to receive injectable colistin for 5 days Control group: injectable placebo of N-acetylcysteine 2 grams per day along with starting to receive injectable colistin for 5 days

Main outcome variables

Urinary N-acetyl-beta-D glucosaminidase(NAG) level, renal function changes according to Risk, Injury, Failure, Loss and end-stage kidney disease (RIFLE) criteria

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200328046886N5**
Registration date: **2023-10-21, 1402/07/29**
Registration timing: **prospective**

Last update: **2023-10-21, 1402/07/29**
Update count: **0**

Registration date

2023-10-21, 1402/07/29

Registrant information

Name

Hamideh Abbaspour

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

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Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-10-23, 1402/08/01

Expected recruitment end date

2024-06-20, 1403/03/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of Effect of N-acetylcysteine On Rate and Severity of Colistin Nephrotoxicity: A Randomized Double-blind Placebo-controlled Trial

Public title
Evaluation of the effect of NAC in colistin-induced nephrotoxicity
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Patients over 18 years old Use of colistin for five days or longer as IV antimicrobial therapy in patients with nosocomial infections Obtaining a written informed consent form from all patients or their guardians
Exclusion criteria:
Receive NAC less than 24 hours before the first dose of colistin Patients undergoing hemodialysis or peritoneal dialysis Receiving contrast material for radiological imaging Pregnant and lactating women Known allergy to colistin or N-acetylcysteine (NAC) Patient with recent history of cardiopulmonary resuscitation Patients with systolic blood pressure <90 mmHg GFR<60 ml/min
Age
From **18 years** old
Gender
Both

Phase
2-3
Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **48**
Randomization (investigator's opinion)
Randomized
Randomization description
To perform randomization, a list of all eligible patients will be prepared first. Using the Excel program, a unique 4-digit code (unique ID) will be considered for each patient. Patients will be placed in two N-acetylcysteine (NAC) and placebo groups based on blocks of 4. The grouping of patients and the type of intervention received are at the disposal of the first project manager, and the patient, the clinical pharmacy assistant who is in charge of clinical evaluations, and the statistical analyst will not know about the grouping of patients. Medicine and placebo will be provided from the same pharmaceutical company. Then, for the control group, 24 cases will be randomly selected using Excel software (Random Sampling) and the remaining cases will be classified as the intervention group.
Blinding (investigator's opinion)
Double blinded
Blinding description
This study will be double blinded. In this way, the patient, doctor and clinical evaluator will not know about the drug used (N-acetylcysteine or placebo). Medicines and placebos are prepared from a pharmaceutical company and are used for each patient in a similar pharmaceutical form marked with a four-digit code.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Mazandaran University of Medical Sciencel
Street address
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Mazandaran
Postal code
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Approval date
2023-08-22, 1402/05/31
Ethics committee reference number
IR.MAZUMS.REC.1402.325

Health conditions studied

1

Description of health condition studied
nephrotoxicity
ICD-10 code
N14.1
ICD-10 code description
Nephropathy induced by other drugs, medicaments and biological substances

Primary outcomes

1

Description
Urinary N-acetyl-beta-D glucosaminidase (NAG) level
Timepoint
First and fifth day of study
Method of measurement
Through the N-acetyl-beta-D glucosaminidase (NAG) urinary measurement kit

2

Description
Severity of kidney damage

Timepoint
Daily during the intervention period
Method of measurement
RIFLE classification system

Secondary outcomes

empty

Intervention groups

1

Description
In the intervention group, patients will be given N-Acetylcysteine (NAC) at a dose of 2 gr intravenously once a day for 5 days along with colistin with a loading dose of 300 mg colistin base activity(CBA) (~9 million IU) and a maintenance dose of 275-360 mg CBA (~9-10.9 million IU) infused in two divided doses every 12 hours for half an hour. Patients with reduced kidney function will receive the dose based on GFR as below: CrCl ≥90 mL/minute: 360 mg CBA/dayCrCl 80 to <90 mL/minute: 340 mg CBA/dayCrCl 70 to <80 mL/minute: 300 mg CBA/dayCrCl 60 to <70 mL/minute: 275 mg CBA/day
Category
Prevention

2

Description
In the control group of patients, the placebo injection form of N-acetylcysteine with a dose of 2 grams intravenously once a day for 5 days along with colistin with a loading dose of 300 mg colistin base activity(CBA) (~9 million IU) and a maintenance dose of 275-360 mg CBA (~9-10.9 million IU) infused in two divided doses every 12 hours for half an hour. Patients with reduced kidney function will receive the dose based on GFR as below: CrCl ≥90 mL/minute: 360 mg CBA/dayCrCl 80 to <90 mL/minute: 340 mg CBA/dayCrCl 70 to <80 mL/minute: 300 mg CBA/dayCrCl 60 to <70 mL/minute: 275 mg CBA/day
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Fatemeh Zahra Hospital
Full name of responsible person
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Sponsors / Funding sources

1

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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
Mazandaran 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
Hamideh abbaspour kasgari

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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
There are no plans to publish the study protocol separately as it is available on IRCT
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
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is 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
No - There is not a plan to make this available
Title and more details about the data/document
Data can be shared after publication
When the data will become available and for how long
Starting 1 month after publication
To whom data/document is available
Researchers working in academic and scientific institutions
Under which criteria data/document could be used
Clinical use and future meta-analyses
From where data/document is obtainable
Hamideh Abbaspour Kasgari - Dr.abbaspour1@yahoo.com
What processes are involved for a request to access data/document
Send an email to Dr. Hamideh Abbaspour Kasgari
Comments