Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Jul 2026

Effect of increasing the duration of Colistin infusion on nephrotoxicity

Protocol summary

Study aim
Effect of increasing the duration of Colistin infusion on nephrotoxicity

Design
Randomized controlled clinical trial

Settings and conduct
Al-Zahra Hospital and Amin Hospital, affiliated to Isfahan University of Medical Sciences

Participants/Inclusion and exclusion criteria
Inclusion criteria: Age 18 to 50 years Receiving colistin at a dose of 4.5 million units every 12 hours (or an equivalent dose according to the patient's kidney function) Creatinine clearance above 50 ml/min at the beginning of the study No history of acute kidney injury (based on history and medical history) Failure to receive other nephrotoxic drugs such as aminoglycosides, amphotericin B, cyclosporine, tacrolimus, furosemide, and NSAIDs Not receiving other antioxidant supplements such as vitamins C and E Exclusion criteria: Age less than 18 years Recent use of colistin in the last seven days Use of colistin in less than three days Dialysis before starting treatment

Intervention groups
For the people in the intervention group, colistin will be prescribed as a long-term infusion (6 hours), and the control group will receive colistin with the usual 1-hour administration method.

Main outcome variables
Blood samples were taken from the patients of both groups before the start of the treatment, during the treatment on an average day, and 12 hours after the last dose of colistin on the tenth day of treatment with this antibiotic (before receiving any other dose of colistin)، and the level of serum creatinine (SCr) and blood urea nitrogen (BUN) will be determined. Creatinine clearance (CrCl) will also be calculated using the CKD-EPI formula. The clinical response of colistin will be evaluated by the complete or partial recovery of fever, leukocytosis, and signs and symptoms of related infections at the end of treatment. Clinical failure is defined as non-fulfillment of all clinical response criteria.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20160713028901N5**
Registration date: **2024-01-10, 1402/10/20**
Registration timing: **prospective**

Last update: **2024-01-10, 1402/10/20**
Update count: **0**

Registration date
2024-01-10, 1402/10/20

Registrant information

Name
Shirinsadat Badri

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 31 3792 7068

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2024-01-20, 1402/10/30

Expected recruitment end date
2025-01-19, 1403/10/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Effect of increasing the duration of Colistin infusion on nephrotoxicity

Public title
Colistin infusion
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Age 18 to 50 years Receiving colistin at a dose of 4.5 million units every 12 hours (or an equivalent dose according to the patient's kidney function) Creatinine clearance above 50 ml/min at the beginning of the study No history of acute kidney injury (based on history and medical history) Failure to receive other nephrotoxic drugs such as aminoglycosides, amphotericin B, cyclosporine, tacrolimus, furosemide and NSAIDs Not receiving other antioxidant supplements such as vitamins C and E
Exclusion criteria:
Recent use of colistin in the last 7 days Using colistin for less than 3 days Dialysis before starting treatment
Age
From **18 years** old to **50 years** old
Gender
Both

Phase
4
Groups that have been masked
No information
Sample size
Target sample size: **30**
Randomization (investigator's opinion)
Randomized
Randomization description
Block randomization method using blocks of four. Information such as the number of treatment groups (2 main intervention groups, for example, A and control for example B), the size of the blocks (a multiple of the number of groups that will be chosen in this study to reduce the complexity of the work, size 4) and the total number of patients (sample size 40 people) to the internet software machines specific for this calculation (for example available at https://www.sealedenvelope.com/simple-randomiser/v1/lists) and according to the codes that are included in the final analysis (including the number of particular groups 4 of which will be 17 groups) is obtained; each of the patients who enter the study is assigned a code that will determine the type of group. Blocking is usually done to balance the number of samples assigned to each. The studied groups will be used. In this method, equal blocking will be used. In this way, the samples will be randomized as much as possible in the same way in two groups.
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
Vice Chancellor of Research, Isfahan University of Medical Sciences (Research Ethics Committee)
Street address
Hezar jerib
City
Isfahan
Province
Isfehan
Postal code
8174673461
Approval date
2023-06-20, 1402/03/30
Ethics committee reference number
IR.MUI.RESEARCH.REC.1402.110

Health conditions studied

1

Description of health condition studied
Kidney failure
ICD-10 code
N17
ICD-10 code description
Acute kidney failure

Primary outcomes

1

Description
Serum creatinine level (SCr)
Timepoint
before starting the treatment, during the treatment for one day in between and also 12 hours after the last dose of colistin on the tenth day of treatment with this antibiotic (before receiving any other dose of colistin)
Method of measurement
Hospital laboratory

2

Description
blood urea nitrogen (BUN)
Timepoint
before starting the treatment, during the treatment for one day in between and also 12 hours after the last dose of colistin on the tenth day of treatment with this antibiotic (before receiving any other dose of colistin)

Method of measurement
Hospital laboratory

3

Description
creatinine clearance (CrCl)
Timepoint
before starting the treatment, during the treatment for one day in between and also 12 hours after the last dose of colistin on the tenth day of treatment with this antibiotic (before receiving any other dose of colistin)
Method of measurement
calculating by equation

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: For people in the intervention group, colistin will be prescribed as a long-term infusion (6 hours). People who, for any reason, received the drug colistin with a standard dose of 150 mg (equivalent to 4.5 million units of sodium colistimethate) or a dose according to their renal function every 12 hours and who meet the other criteria for entering the study, were randomly They will be placed in two intervention and control groups. Demographic and clinical characteristics of patients, including age, sex, body weight, current illness, past medical history, history of underlying kidney disease, other antibiotic treatments, duration of colistin use, concurrently prescribed drugs, inpatient department, and diagnosis (indication for drug use) and drug-related points including date, time, dose and duration of injection will be recorded. For the people in the intervention group, colistin will be prescribed as a long-term infusion (6 hours). The drug is infused in 500 ml of normal saline without adding other medications through a separate line. The drug dose may be adjusted according to the patient's renal function to consider clinical performance patterns. The physician will evaluate the patient's clinical symptoms during the treatment period.
Category
Treatment - Drugs

2

Description
Control group: The control group will receive colistin with the usual 1-hour administration method. People who, for any reason, received the drug colistin with a standard dose of 150 mg (equivalent to 4.5 million units of sodium colistimethate) or a dose according to their renal function every 12 hours and who meet the other criteria for entering the study, were randomly They will be placed in two intervention and control groups. Demographic and clinical characteristics of patients, including age, sex, body weight, current illness, past medical history, history of underlying kidney disease, other antibiotic treatments, duration of colistin use, concurrently prescribed drugs, inpatient department, and diagnosis (indication for drug use) and drug-related points including date, time, dose and duration of injection will be recorded. The control group will receive colistin with the usual 1-hour administration method. The drug is infused in 500 ml of normal saline without adding other medications through a separate line. The drug dose may be adjusted according to the patient's renal function to consider clinical performance patterns. The physician will evaluate the patient's clinical symptoms during the treatment period.
Category
Treatment - Drugs

Recruitment centers

1

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

1

Sponsor
Name of organization / entity
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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
Shirinsadat Badri
Position
Associate professor
Latest degree
Ph.D.
Other areas of specialty/work
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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
confidentiality
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
Yes - There is a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
Not applicable
Title and more details about the data/document
in the form of a student thesis
When the data will become available and for how long
After the student's defense, two years after the start of the project
To whom data/document is available
Academics
Under which criteria data/document could be used
Scientific exploitation

From where data/document is obtainable

Electronic library of Isfahan University of Medical Sciences

What processes are involved for a request to access data/document

Refer to the electronic library website of Isfahan University of Medical Sciences

Comments