# 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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**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**
Dr 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**
Gholamreza Asgari
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research@mui.ac.ir
**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.
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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**