

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

16 Sep 2026

### Evaluation the effect of prolonging the duration of administration of Colistin infusion on the Colistin-induced nephrotoxicity

#### Protocol summary

2023-05-27, 1402/03/06

##### Study aim

Evaluation the effect of prolonging the duration of administration of Colistin infusion on the Colistin-induced nephrotoxicity

##### Design

This study is a clinical trial. The number of 72 patients in Amir al-Momenin hospital in Arak who are candidates for colistin will be included in the study. They were randomly divided into 2 groups

##### Settings and conduct

This study is a clinical trial. The number of 72 patients in Amir al-Momenin hospital in Arak who are candidates for colistin will be included in the study. In the intervention group, the duration of colistin infusion is 1 million units in 2 hours.

##### Participants/Inclusion and exclusion criteria

At least 18 years old A patient receiving colistin Infection with Multidrug resistance organism Sputum culture be positive with Acinetobacter baumannii , Klebsiella pneumoniae

##### Intervention groups

Intervention group (Colistin infusion: 1 million units in a 2 hours) Control group (Infusion in 20 minutes)

##### Main outcome variables

drug toxicity

#### Registrant information

##### Name

Sina Hashemi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 86 3314 1382

##### Email address

h99.sina@gmail.com

#### Recruitment status

##### Recruitment complete

#### Funding source

#### Expected recruitment start date

2023-03-04, 1401/12/13

#### Expected recruitment end date

2023-12-04, 1402/09/13

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

Evaluation the effect of prolonging the duration of administration of Colistin infusion on the Colistin-induced nephrotoxicity

#### Public title

Evaluation the effect of prolonging the duration of administration of Colistin infusion on the Colistin-induced nephrotoxicity

#### Purpose

Prevention

#### Inclusion/Exclusion criteria

##### Inclusion criteria:

At least 18 years old Infection with Multidrug resistance

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20230225057533N1**

Registration date: **2023-05-27, 1402/03/06**

Registration timing: **registered\_while\_recruiting**

Last update: **2023-05-27, 1402/03/06**

Update count: **0**

##### Registration date

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |  |                                                                                          |  |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--|------------------------------------------------------------------------------------------|--|
| organism Sputum culture be positive with Acinetobacter baumannii , Klebsiella pneumoniae                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |  | <b>Province</b><br>Markazi                                                               |  |
| <b>Exclusion criteria:</b><br>Discontinue treatment with colistin Receiving other nephrotoxic drugs at the same time Oliguria (urine output less than 500 cc in 24 hours) Hypotension due to a reason other than sepsis (embolism, MI, hypovolemic shock), receiving NSAIDs Receive albumin receiving contrast agents Estimated glomerular filtration rate (eGFR) less than 5 mL/min/1.73 m2                                                                                                                                                                                                                                                                                                                     |  | <b>Postal code</b><br>38149578558                                                        |  |
| <b>Age</b><br>From 18 years old                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |  | <b>Approval date</b><br>2023-01-07, 1401/10/17                                           |  |
| <b>Gender</b><br>Both                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |  | <b>Ethics committee reference number</b><br>IR.ARAKMU.REC.1401.295                       |  |
| <b>Phase</b><br>2-3                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |  | <b>Health conditions studied</b>                                                         |  |
| <b>Groups that have been masked</b><br>No information                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |  | <b>1</b>                                                                                 |  |
| <b>Sample size</b><br>Target sample size: 72                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |  | <b>Description of health condition studied</b><br>Nephrotoxicity                         |  |
| <b>Randomization (investigator's opinion)</b><br>Randomized                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |  | <b>ICD-10 code</b>                                                                       |  |
| <b>Randomization description</b><br>Simple randomization with a table of random numbers in dividing groups into intervention and control groups Randomization method: simple randomization. Randomization is done in a simple way using a table of random numbers. In this way, odd numbers are assigned to the intervention group and even numbers are assigned to the control group. This work should be continued until the number of samples is completed. Researcher moves from a selected point randomly with a pen. In this case, it may be divided into two groups of numbers larger or smaller than the total number of samples. Researcher should only confirm numbers smaller than the total samples. |  | <b>ICD-10 code description</b>                                                           |  |
| <b>Blinding (investigator's opinion)</b><br>Not blinded                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |  | <b>Primary outcomes</b>                                                                  |  |
| <b>Blinding description</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |  | <b>1</b>                                                                                 |  |
| <b>Placebo</b><br>Not used                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |  | <b>Description</b><br>Level of Creatinine and BUN                                        |  |
| <b>Assignment</b><br>Parallel                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |  | <b>Timepoint</b><br>Daily                                                                |  |
| <b>Other design features</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |  | <b>Method of measurement</b><br>Blood test                                               |  |
| <b>Secondary Ids</b><br>empty                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |  | <b>Secondary outcomes</b><br>empty                                                       |  |
| <b>Ethics committees</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |  | <b>Intervention groups</b>                                                               |  |
| <b>1</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |  | <b>1</b>                                                                                 |  |
| <b>Ethics committee</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |  | <b>Description</b><br>Intervention group: Infusion of colistin 1million unit in 2 hours  |  |
| <b>Name of ethics committee</b><br>Arak University of Medical Sciences (Research Ethics Committee)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |  | <b>Category</b><br>Treatment - Drugs                                                     |  |
| <b>Street address</b><br>No.1, Faculties Building, University Complex of the Prophet (PBUH), Basij Square , Arak                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |  | <b>2</b>                                                                                 |  |
| <b>City</b><br>Arak                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |  | <b>Description</b><br>Control group: Control group: Clostin drug infusion for 20 minutes |  |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |  | <b>Category</b><br>Treatment - Drugs                                                     |  |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |  | <b>Recruitment centers</b>                                                               |  |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |  | <b>1</b>                                                                                 |  |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |  | <b>Recruitment center</b>                                                                |  |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |  | <b>Name of recruitment center</b><br>Amir al momenin hospital                            |  |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |  | <b>Full name of responsible person</b><br>Dr Somayeh Shabib                              |  |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |  | <b>Street address</b><br>No 1, Amir al-Momenin (AS) educational and                      |  |

therapeutic center, Basij Square-next to medical school,Arak

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## Sponsors / Funding sources

### 1

**Sponsor**

**Name of organization / entity**

Arak University of Medical Sciences

**Full name of responsible person**

Dr Alireza Amani

**Street address**

No.1, Faculties Building,University Complex of the Prophet (PBUH),Basij Square ,Arak

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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**

Arak 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**

Arak University of Medical Sciences

**Full name of responsible person**

Dr Somayeh Shabib

**Position**

Professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Clinical Pharmacotherapy

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## Person responsible for scientific inquiries

**Contact**

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**Full name of responsible person**

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Professor

**Latest degree**

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**Other areas of specialty/work**

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## Person responsible for updating data

**Contact**

**Name of organization / entity**

Arak University of Medical Sciences

**Full name of responsible person**

Sina Hashemi

**Position**

Student

**Latest degree**

A Level or less

**Other areas of specialty/work**

General Practitioner

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

**Study Protocol**

Undecided - It is not yet known if there will be a plan to make this available

**Statistical Analysis Plan**

Undecided - It is not yet known if there will be a plan to make this available

**Informed Consent Form**

Undecided - It is not yet known if there will be a plan to make this available

**Clinical Study Report**

Undecided - It is not yet known if there will be 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**

Undecided - It is not yet known if there will be a plan to make this available