

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 Jun 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

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

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

organism Sputum culture be positive with Acinetobacter baumannii , Klebsiella pneumoniae

Exclusion criteria:

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

Age

From **18 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **72**

Randomization (investigator's opinion)

Randomized

Randomization description

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.

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

Arak University of Medical Sciences (Research Ethics Committee)

Street address

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

City

Arak

Province

Markazi

Postal code

38149578558

Approval date

2023-01-07, 1401/10/17

Ethics committee reference number

IR.ARAKMU.REC.1401.295

Health conditions studied

1

Description of health condition studied

Nephrotoxicity

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Level of Creatinine and BUN

Timepoint

Daily

Method of measurement

Blood test

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Infusion of colistin 1million unit in 2 hours

Category

Treatment - Drugs

2

Description

Control group: Control group: Clostin drug infusion for 20 minutes

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Amir al momenin hospital

Full name of responsible person

Dr Somayeh Shabib

Street address

No 1, Amir al-Momenin (AS) educational and

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

City

Arak

Province

Markazi

Postal code

3848176941

Phone

+98 86 3417 3619

Email

Shabib333@gmail.com

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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dramani.ortho@yahoo.com

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

Street address

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

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38481-7-6341

Phone

009833838392

Email

shabib333@gmail.com

Person responsible for scientific 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 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

Street address

No 1 , Yas 2 Alley , Habib Ibn Mazaher Alley , Shahid

Shiroudi St

City

Arak

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Markazi

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3819768481

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Email

h99.sina@gmail.com

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