

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

21 Jun 2026

### Comparative study of the renal toxicity of dosage regimen containing high and conventional doses of colistin with monitoring of novel biomarkers of acute kidney injury

#### Protocol summary

##### Summary

Reemergence of colistin, an old antibiotic, because of world wide increase in hospital acquired infections due to multi drug resistant gram negative organisms result in more study about its pharmacokinetic and suggestion of new dosing regimen. New regimen include a loading doses of 9 million units and maintenance doses of 4.5 million units every 12 hours, compared to conventional dosing of 1-2 million units every 8 hours. Concern about nephrotoxicity of these high doses leading to design of this randomized controlled trial to compare nephrotoxicity of these two regimens. 40 patients candidate for colistin therapy included and randomized in two 20 patients groups, one group received high dose regimen and another one received low dose regimen. Blood samples was drawn on day 1 (before first dose), day 3, 5, 7 and 10 of treatment, serum separated and then stored at - 70 degree centigrade. Cystatin c and NGAL, sensitive biomarkers of early detection of acute kidney injury, was measured and compared in groups.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2014090614693N5**

Registration date: **2014-09-23, 1393/07/01**

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

Last update:

Update count: **0**

##### Registration date

2014-09-23, 1393/07/01

##### Registrant information

###### Name

Zahra Sahraei

##### Name of organization / entity

Faculty of pharmacy, Shahid beheshti university of medical sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 8887 3704

##### Email address

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##### Recruitment status

**Recruitment complete**

##### Funding source

Shahid Beheshti University of Medical Sciences, Faculty of Pharmacy.

##### Expected recruitment start date

2014-03-20, 1392/12/29

##### Expected recruitment end date

2015-09-20, 1394/06/29

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparative study of the renal toxicity of dosage regimen containing high and conventional doses of colistin with monitoring of novel biomarkers of acute kidney injury

##### Public title

Comparative study of the renal toxicity of dosage regimen containing high and conventional doses of colistin with monitoring of novel biomarkers of acute kidney injury

##### Purpose

Diagnostic

## **Inclusion/Exclusion criteria**

Inclusion: candidate for colistin therapy; at least 7 days colistin therapy; age 18-65 Exclusion: chronic kidney injury (GFR<60); Acute kidney injury; BMI>35; patient discontent

## **Age**

From **18 years** old to **65 years** old

## **Gender**

Both

## **Phase**

N/A

## **Groups that have been masked**

*No information*

## **Sample size**

Target sample size: **40**

## **Randomization (investigator's opinion)**

Randomized

## **Randomization description**

## **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**

Faculty of Pharmacy, Shahid Beheshti University of Medical Sciences.

##### **Street address**

Niyayesh cross road, Valiasr st.

##### **City**

Tehran

##### **Postal code**

#### **Approval date**

2014-01-21, 1392/11/01

#### **Ethics committee reference number**

268

## **Health conditions studied**

### 1

#### **Description of health condition studied**

patients with hospital acquired infections due to multi drug resistant gram negative organisms

#### **ICD-10 code**

B96.1

#### **ICD-10 code description**

Klebsiella pneumoniae [K. pneumoniae] as the cause of diseases classified to other chapters

### 2

#### **Description of health condition studied**

patients with hospital acquired infections due to multi drug resistant gram negative organisms

#### **ICD-10 code**

A41.8

#### **ICD-10 code description**

Other specified sepsis

### 3

#### **Description of health condition studied**

patients with hospital acquired infections due to multi drug resistant gram negative organisms

#### **ICD-10 code**

B99

#### **ICD-10 code description**

Other and unspecified infectious diseases

## **Primary outcomes**

### 1

#### **Description**

serum cystatin c level

#### **Timepoint**

day 1(before first dose), 3, 5, 7, 10

#### **Method of measurement**

biochemisty kit

## **Secondary outcomes**

### 1

#### **Description**

change in serum creatinin level and GFR

#### **Timepoint**

first 10 days of treatment

#### **Method of measurement**

GFR with cockroft gault equation

### 2

#### **Description**

Added at 2016-08-10: Neutrophil gelatinase-associated lipocalin (NGAL)

#### **Timepoint**

Added at 2016-08-10: day 1, 3, 5, 7, 10

#### **Method of measurement**

Added at 2016-08-10: ELISA kit

## **Intervention groups**

### 1

#### **Description**

In high dose group, the patients receive a loading doses of 9 million units and maintenance doses of 4.5 million units colistin every 12 hours, Blood samples was drawn on day 1 (before first dose), day 3, 5, 7 and 10 of treatment, serum separated and then stored at - 70

degree centigrade.

**Category**

Treatment - Drugs

**2****Description**

In low dose group, the patients receive 2 million units colistin every 8 hours. Blood samples was drawn on day 1 (before first dose), day 3, 5, 7 and 10 of treatment, serum separated and then stored at - 70 degree centigrade.

**Category**

Treatment - Drugs

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Loghman Hakim hospital

**Full name of responsible person**

Dr. Zahra Sahraei

**Street address****City**

Tehran

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Faculty of Pharmacy, Shahid Beheshti university of medical sciences

**Full name of responsible person**

dr. Jamshid Salamzadeh

**Street address**

Niyayesh cross road, Valiasr st.

**City**

Tehran

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Faculty of Pharmacy, Shahid Beheshti university of medical sciences

**Proportion provided by this source**

100

**Public or private sector**

*empty*

**Domestic or foreign origin**

*empty*

**Category of foreign source of funding**

*empty*

**Country of origin****Type of organization providing the funding**

*empty*

**Person responsible for general inquiries****Contact****Name of organization / entity**

Faculty of pharmacy, Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Dr. Atefeh Ordooei Javan

**Position**

Resident of Clinical Pharmacy

**Other areas of specialty/work****Street address**

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atefeh.ordooei.j@gmail.com

**Web page address****Person responsible for scientific inquiries****Contact****Name of organization / entity**

Faculty of Pharmacy, Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Dr. Zahra Sahraei

**Position**

Assistant professor

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**Web page address****Person responsible for updating data****Contact****Sharing plan****Deidentified Individual Participant Data Set (IPD)**

*empty*

**Study Protocol**

*empty*

**Statistical Analysis Plan**

*empty*

**Informed Consent Form**

*empty*

**Clinical Study Report**

*empty*  
**Analytic Code**  
*empty*

**Data Dictionary**  
*empty*