

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

z.sahraei@sbmu.ac.ir

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 drown 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**

Niyayesh cross road, Valiasr st.

City

Tehran

Postal code**Phone**

+98 21 8820 0118

Fax**Email**

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

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

Niyayesh cross road, Valiasr st.

City

Tehran

Postal code**Phone**

+98 21 8820 0118

Fax**Email**

z.sahraei@sbmu.ac.ir

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