Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Evaluating the effect of intravenous magnesium sulphate for prevention of colistin induced Acute Kidney Injury

Protocol summary

Study aim

The main objective: to evaluate the effect of intravenous magnesium sulfate for prevention of colistin induced Acute Kidney Injury (AKI). The specific objective: determining the laboratory information (Mg, BUN and Cr), occurrence of AKI and clinical outcomes (escalation or de-escalation of therapy, length of hospitalization and mortality) of patients receiving colistin and comparing it with colistin + magnesium group.

Design

Two arm parallel group block randomized clinical trial, phase 3 on 96 patients.

Settings and conduct

Patients receiving colistin in Loghman Hakim Hospital who meet inclusion criteria, are divided into 2 equal groups of intervention and control. Each group has 2 blocks of without & with vancomycin to equalize the effect of other nephrotoxic antibiotics. Patients are evaluated 1 week; daily for occurrence of AKI (serum Cr, urinary output) and magnesium level. Exclusion criteria is non-renal AKI, receiving amphotericin or vitamin C, hypo/hypermagnesemia, death, discharge. Secondary outcomes are length of hospitalization, regimen change and death.

Participants/Inclusion and exclusion criteria

Inclusion criteria: age over 18 years, GFR greater than 60 (ml/min), indication of colistin therapy, and magnesium blood level of greater than 1.9 and less than 3 (mg/dl). Non-inclusion criteria: pregnancy.

Intervention groups

Intervention group: colistin with a loading dose of 9-12 mIU as 1-hr infusion and daily maintenance dose of 9-12 mIU divided into 2 infusions & 1hour before each dose of colistin, 1hr infusion of 2g intravenous magnesium sulfate (dissolved in 50 ml of normal saline). Control group: colistin the same as intervention group with no intravenous magnesium.

Main outcome variables

The main outcome of this study: occurrence of Acute Kidney Injury in the first week of colistin therapy (KIDIGO criteria); with variables of serum creatinine and urinary output.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20130917014693N15**
Registration date: **2023-01-12, 1401/10/22**
Registration timing: **prospective**

Last update: **2023-01-12, 1401/10/22**
Update count: **0**

Registration date

2023-01-12, 1401/10/22

Registrant information

Name
Zahra Sahraei

Name of organization / entity
Faculty of pharmacy, Shahid beheshti university of medical sciences

Country
Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-01-21, 1401/11/01

Expected recruitment end date

2024-02-19, 1402/11/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluating the effect of intravenous magnesium sulphate for prevention of colistin induced Acute Kidney Injury

Public title

Evaluating the effects of magnesium in colistin nephrotoxicity

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with indication of colistin therapy patients with GFR> 60ml/min patients with magnesium blood level between 1.9 and 3 mg/dl

Exclusion criteria:

patients younger than 18 years patients with GFR< 60ml/min patients with magnesium blood level of less than 1.9 or more than 3 mg/dl Pregnant patients

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **96**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, block randomization method with aim of elimination of the nephrotoxic effects of vancomycin (the other routinely used nephrotoxic antibiotics) is used. Therfore, this study is designed in 2 blocks of "with and without vancomycin". In each block (with an equal number of patients), patients are placed in two control and intervention groups using a table of random numbers in a ratio of 1:1. The calculated number of samples is 96 patients, which are numbered from 1 to 96 according to the sampling time. To use the table of random numbers, a column and a row are randomly selected, and the 2 digits on the left side of the crossing point is the first selected number. A hypothetical plus is drawn from that number and the numbers placed in that plus are selected. This process continues until half of the total number of samples (48 numbers) is selected, and this numbers will determine the intervention group. The first 24 numbers will be in the intervention group of "with vancomycin" block and the second 24 numbers will be in theintervention group of "without vancomycin" block.

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

Ethics committee of shahid beheshti university of medical sciences

Street address

3rd floor, medical school, Shahid Arabi Street, Yemen Street, Shahid Chamran Highway

City

Tehran

Province

Tehran

Postal code

1983963113

Approval date

2022-10-25, 1401/08/03

Ethics committee reference number

IR.SBMU.PHARMACY.REC.1401.134

Health conditions studied

1

Description of health condition studied

Acute Kidney Injury

ICD-10 code

N17.9

ICD-10 code description

Acute kidney failure, unspecified

Primary outcomes

1

Description

Acute Kidney Injury occurrence

Timepoint

Daily during the first week of colistin therapy

Method of measurement

The Kidney Disease Improving Global Outcomes (KDIGO) criteria for Acute Kidney Injury

Secondary outcomes

1

Description

Escalation or de-escalation of therapy

Timepoint

Daily during the first week of colistin therapy

Method of measurement
Colistin daily dose observation

2

Description
Length of hospitalization
Timepoint
At the time of discharge
Method of measurement
Counting the number of days

3

Description
Death
Timepoint
Daily
Method of measurement
Records Observation

Intervention groups

1

Description
Intervention group: Colistin therapy begins with a dose of 9-12 million IU as 1-hr infusion and maintenance therapy continues after 12 hours of the loading dose, with a daily dose of 9-12 million IU divided into two infusions with 12-hour interval. In the intervention group, one hour before receiving each dose of colistin, 2g (16~mEq) intravenous magnesium sulfate (dissolved in 50 ml of normal saline) is infused within one hour.
Category
Prevention

2

Description
Control group: Colistin therapy begins with a dose of 9-12 million IU as 1-hr infusion and maintenance therapy continues after 12 hours of the loading dose, with a daily dose of 9-12 million IU divided into two infusions with 12-hour interval.
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Loghman Hakim hospital
Full name of responsible person
Zahra Sahraei
Street address
Loghman Hakim hospital, Kamali Street, Lashgar Crossroads, South Kargar Street, Tehran
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Dr Afshin Zarghi
Street address
3 rd floor, School of Medicine, Arabi Street, Yaman street, Chamran Highway
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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
Shahid Beheshti 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
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Zahra Sahraei
Position
Associated Professor
Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is 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

Title and more details about the data/document

All data can potentially be shared after blinding.

When the data will become available and for how long

Six months after the results are published

To whom data/document is available

Academic institution's researchers

Under which criteria data/document could be used

Research purposes and meta-analysis

From where data/document is obtainable

Dr. Zahra Sahraei, Loghman Hakim Hospital, Kamali St, South Kargar St, Tehran

What processes are involved for a request to access data/document

Official letter to researchers

Comments