Clinical Trial Protocol
Iranian Registry of Clinical Trials

15 Jul 2026

Study of Clinical outcomes and serum concentration of meropenem in patients with acute kidney injury treated with two different dosing regimens

Protocol summary

Study aim

1-Study of Clinical outcomes and serum concentration of meropenem in patients with acute kidney injury treated with two different dosing regimens 2-Determine the percentage of patients who receive two standard and adjustment regimens to get the appropriate clinical response and acceptable serum drug level

Design

Randomised Clinical Trial, parallel group

Settings and conduct

This study will be carried out in Imam Hossein Hospital of Tehran.All patients receive the standard dose of meropenem for up to 48 hours.Then blood sample is taken from patients for measurement of peak and trough concentrations of meropenem.Then patients randomly placed in one of two groups,once that receives a standard dose until the end of the treatment, and the other group receives based on the renal functionIn, between five to seven days, the blood sample is taken to measurement of peak and trough concentrations of meropenem, and daily monitoring of the clinical symptoms of the patient is performed to assess the response to treatment.

Participants/Inclusion and exclusion criteria

1- Need to be treated with meropenem 2- Minimally increase the level of creatinine from the base level by 1.5 or at least increase the creatinine level by more than 0.3mg / dl, or at least decrease by more than 25% of GFR or urinary excretion less than 0.5ml / kg / h for more than 6 hours. 3. Age older than 18 years

Intervention groups

All patients receive the standard dose of meropenem for up to 48 hours and then randomly placed in one of two groups,once that receives a standard dose until the end of the treatment, and the other group receives based on the renal function

Main outcome variables

Serum concentration of Meropenem,Clinical outcomes

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160412027346N5**
Registration date: **2019-01-19, 1397/10/29**
Registration timing: **prospective**

Last update: **2019-01-19, 1397/10/29**
Update count: **0**

Registration date

2019-01-19, 1397/10/29

Registrant information

Name
Shadi Ziaie
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Country
Iran (Islamic Republic of)
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+98 21 8887 3704
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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-01-21, 1397/11/01

Expected recruitment end date

2020-01-21, 1398/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Study of Clinical outcomes and serum concentration of meropenem in patients with acute kidney injury treated with two different dosing regimens

Public title

"Study of Clinical outcomes and serum concentration of Meropenem in acute kidney injury"

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Acute kidney injury Recepient of Meropenem Age over 18 year

Exclusion criteria:

History of chronic kidney disease Get chronic or emergency dialysis History of seizure History of allergy to beta-lactam Pregnancy and lactation

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **34**

Randomization (investigator's opinion)

Randomized

Randomization description

Permuted Block randominization,blocksizes:4 ,with using statistical software

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

Niayesh Highway, Valiasr Ave, Tehran

City

Tehran

Province

Tehran

Postal code

1985717443

Approval date

2018-05-28, 1397/03/07

Ethics committee reference number

IR.SBMU.PHARMACY.REC.1397.038

Health conditions studied

1

Description of health condition studied

Acute kidney disease

ICD-10 code

N17

ICD-10 code description

Acute kidney failure

Primary outcomes

1

Description

Serum concentration of Meropenem

Timepoint

Measurement of serum concentration of Meropenem in half an hour before and one hour after infusion on three and fifth day of drug injection

Method of measurement

HPLC

Secondary outcomes

1

Description

Clinical outcomes

Timepoint

Daily

Method of measurement

Clinical Pulmonary infection Score

2

Description

Serum creatinin

Timepoint

Daily

Method of measurement

Laboratory method

Intervention groups

1

Description

Intervention group: recieving Meropenem 1 gram three times a day

Category

Treatment - Drugs

2

Description
Intervention group: recieving Meropenem with regulated dose based on daily creatinine level
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Hossin hospital
Full name of responsible person
Rezvan Hassanpour
Street address
Niayesh Highway, Valiasr Ave, Tehran
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
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naderi@sbmu.ac.ir
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
Rezvan Hassanpour
Position
Resident
Latest degree
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Person responsible for updating data

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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
Yes - There is a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Yes - There is a plan to make this available

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
At the end of the study all the data after blinding and statistical analysis based on what mentioned in methodology will be extracted and published online as a scientific paper

When the data will become available and for how long
6 months after publishing the results

To whom data/document is available
responsible investigator, Physicians, academician investigators

Under which criteria data/document could be used
only with permission of responsible investigator or regulatories

From where data/document is obtainable
Responsible investigator

What processes are involved for a request to access data/document
Through contacting with responsible investigator

Comments