

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

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

Protocol summary

Serum concentration of Meropenem, Clinical outcomes

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 function. In, 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

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)

Phone

+98 21 8887 3704

Email address

shadiziaie@sbmu.ac.ir

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 Receptient 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 randomization,block sizes: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: receiving 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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Email

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Nima Naderi

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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

Medical doctor

Other areas of specialty/work

Medical Pharmacy

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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