Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jul 2026

Evaluation of prevalence of Augmented renal clearance (ARC) and serum concentration of Meropenem with two different dosing regimens in critically ill patients

Protocol summary

Study aim
Evaluation of prevalence of Augmented renal clearance (ARC) and serum concentration of Meropenem with two different dosing regimens in patients with ARC

Design
Pre-post intervention, randomized, open label clinical trial

Settings and conduct
On the first day of the study, patients will be evaluated according to Augmented renal clearance (ARC) and Augmented renal clearance in trauma intensive Care (ARCTIC) scoring systems and for patients who categorized as high-risk based on these systems, 12-hour creatinine clearance will be measured on days 0, 3, 7,10 and 14. Subjects with creatinine clearance 130 ml/min and above will be recruited. For patients who will be treated with meropenem 3g daily (1 gram three times a day), based on physician in charge decision, after 24 hours, blood samples will be drawn, one hour after end of the infusion (peak concentration) and half an hour before receiving the next dose (trough concentration), in order to measure the meropenem serum concentration.Then the dosage adjustment will be done and will increase to 6g daily (2 grams three times a day). Next set of same blood samples will be drawn 24 hours after dose change to measure new peak and trough meropenem serum concentrations.

Participants/Inclusion and exclusion criteria
Inclusion criteria: serum creatinin 0.7mg/dl and lower,Sequential Organ Failure Assessment (SOFA) score 4 and lower , Augmented renal clearance (ARC) scoring 7 and higher ,Augmented renal clearance in trauma intensive Care (ARCTIC) scoring 7 and higher, 12 hour - Clearance creatinin 130 ml/min and higher Exclusion criteria: Age lower than 18 , Pregnancy and Lactation

Intervention groups
First receive meropenem(Ronak daru) with a dose of 1 g three times a day infusion over 4 hour , then dose up to to 2 g three times a day.

Main outcome variables
Serum concentration of meropenem

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20120703010178N19**
Registration date: **2020-02-07, 1398/11/18**
Registration timing: **registered_while_recruiting**

Last update: **2020-02-07, 1398/11/18**
Update count: **0**

Registration date
2020-02-07, 1398/11/18

Registrant information

Name
Mohammad Sistanizad

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 21 8820 0087

Email address
sistanizadm@sbmu.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-06-22, 1398/04/01

Expected recruitment end date
2020-03-19, 1398/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of prevalence of Augmented renal clearance (ARC) and serum concentration of Meropenem with two different dosing regimens in critically ill patients

Public title

Augmented renal clearance (ARC) and Meropenem concentration

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

serum creatinin 0.7mg/dl and lower Sequential Organ Failure Assessment (SOFA) score 4 and lower Augmented renal clearance (ARC) scoring 7 and higher Augmented renal clearance in trauma intensive Care (ARCTIC) scoring 7 and higher 12 hour - Clearance creatinin 130 ml/min and higher

Exclusion criteria:

Pregnancy and Lactation Age lower than 18 yr

Age

From **18 years** old to **75 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **20**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shahid Beheshti University of Medical Sciences, Faculties of Pharmacy and Nursin

Street address

Faculty of pharmacy, Niayesh and Vali-e-Asr junction

City

Tehran

Province

Tehran

Postal code

1991953381

Approval date

2018-05-28, 1397/03/07

Ethics committee reference number

IR.SBMU.PHARMACY.REC.1398.164

Health conditions studied

1

Description of health condition studied

Augmented renal clearance (ARC)

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Serum concentration of Meropenem

Timepoint

1 hour after end of infusion, 30 minute before next dose

Method of measurement

HPLC

2

Description

Serum creatinin

Timepoint

Daily from the beginning of the study to the 14th day of the study

Method of measurement

Laboratory apparatus, Calorimetric method

3

Description

Urine volume

Timepoint

0,3,7,10,14 day of enter to study

Method of measurement

Urine bag

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Patients with creatinine clearance of more than or equal to 130 ml/min, based on 12-hr urine collection, who receive meropenem (Ronakpharm, Iran)

will be recruited in the study. Study subjects will receive meropenem, 1 g three times daily as 4-hr infusion. After 24 hours, at steady state, two blood samples, 1 hour after termination of infusion and 0.5 hour before next dose, will be gathered. Then the dose of meropenem will be increased to 2 g three times in day and again, after 24 hours, one hour after end of infusion and half an hour before receiving the next dose of meropenem the blood sample will be drawn. Meropenem concentration will be determined by HPLC method.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Intensive Care Unit,Imam Hossein medical center

Full name of responsible person

Mohammad Sistanizad

Street address

Imam Hossein medical center,Shahid Madani Street, Nezam Abad Neighborhood

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Afshin Zarghi

Street address

3rd Floor,School of Medicin.Next to Taleghani Hospital,Evin,Shahid Chamran High Way

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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

Mohammad Sistanizad

Position

Associated Professor/Clinical Pharmacy Specialist

Latest degree

Specialist

Other areas of specialty/work

Medical Pharmacy

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Position

Associated Professor,Clinical Pharmacy Specialist

Latest degree

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Person responsible for updating data

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Rezvan Hassanpour

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Resident

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Medical doctor

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be 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