

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jul 2026

Investigation of pharmacokinetic and clinical outcomes of various meropenem regimens in patients with ventilator-associated pneumonia and augmented renal clearance

Protocol summary

Study aim

Investigation of pharmacokinetic and clinical outcomes of various meropenem regimens in patients with ventilator-associated pneumonia and augmented renal clearance

Design

Randomized controlled clinical trial, phase 3, 60 patients. In order to randomization, online randomization website is used.

Settings and conduct

Study is conducted in ICU ward of Loghman Hakim Hospital. Patients with pneumonia receiving meropenem and high risk for ARC are recruited and creatinine clearance is measured using patient's urine collected during 8 hours in days 1,3,5.

Participants/Inclusion and exclusion criteria

patients with augmented renal clearance and ventilator associated pneumonia

Intervention groups

receiving 1 mg meropenem TDS infused over 6 hours -
receiving 2 mg meropenem TDS infused over 3 hours

Main outcome variables

FT>MIC in at least 50% of dose interval time; resolution of fever, leukocytosis, decline in secretions, oxygenation improvement, no new pulmonary infiltration, no new positive tracheal culture, decrease in intubation time and hospitalization, ESR, CRP, lactate serum level

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20130917014693N12**

Registration date: **2020-09-29, 1399/07/08**

Registration timing: **registered_while_recruiting**

Last update: **2020-09-29, 1399/07/08**

Update count: **0**

Registration date

2020-09-29, 1399/07/08

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

Expected recruitment start date

2020-05-21, 1399/03/01

Expected recruitment end date

2021-02-19, 1399/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigation of pharmacokinetic and clinical outcomes of various meropenem regimens in patients with ventilator-associated pneumonia and augmented renal clearance

Public title

Various types of meropenem administration in patients with VAP and ARC

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Definitive or probable diagnosis of VAP based upon CPIS
Patients with high probability for ARC according to ARC scoring systems. (score>7) Patients receiving meropenem Patient`s serum creatinine level less than 1.3 mg/dL Patients >18 years old

Exclusion criteria:

Patients sensitive to meropenem Infection due to gram-positive bacteria Patients diagnosed with acute kidney injury Patients non-responsive to meropenem during the first 7 days of treatment and therefore needing medication change

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **60**

More than 1 sample in each individual

Number of samples in each individual: **6**

2 blood samples on days 2,3,5 of treatment

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, block randomization method is used and 10 blocks consisting of 6 patients are generated through online randomization website. In each block 2 patients are allocated to standard group (1 mg meropenem TDS, infused over 3 hours) and 4 patients are allocated to intervention groups; 2 patients receiving 2 mg meropenem TDS, infused over 3 hours and 2 patients receiving 1 mg meropenem TDS, infused over 6 hours. Then, sampling will be done through individual sampling method.

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**

Vice-Chancellor in Research Affairs - Shahid Beheshti University of Medical Sciences

Street address

3 rd floor, School of Medicine, Evin St, Shahid Chamran Highway

City

tehran

Province

Tehran

Postal code

1983963113

Approval date

2019-07-14, 1398/04/23

Ethics committee reference number

IR.SBMU.PHARMACY.REC.1398.095

Health conditions studied**1****Description of health condition studied**

ventilator associated pneumonia

ICD-10 code

J95.851

ICD-10 code description

Ventilator associated pneumonia

Primary outcomes**1****Description**

ft>MIC in at least 50% of dose time interval

Timepoint

days 2,3,5 during meropenem administration

Method of measurement

measuring meropenem plasma concentration by HPLC

Secondary outcomes**1****Description**

improvement in clinical factors

Timepoint

daily

Method of measurement

observation

Intervention groups**1****Description**

Control group: receiving 1 mg meropenem TDS infused over 3 hours

Category

Treatment - Drugs

2**Description**

Intervention group: receiving 2 mg meropenem TDS

infused over 3 hours

Category

Treatment - Drugs

3

Description

Intervention group: receiving 1 mg meropenem TDS
infused over 6 hours

Category

Treatment - Drugs

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 St, Makhsoos St

City

tehran

Province

Tehran

Postal code

1333635445

Phone

+98 21 5541 9005

Email

zahra.sahraei@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Afshin Zarghi

Street address

3 rd floor, School of Medicine, Evin St, Shahid
Chamran Highway

City

tehran

Province

Tehran

Postal code

1983963113

Phone

+98 21 23871

Email

mpd@sbm.ac.ir

Grant name

Grant code / Reference number

**Is the source of funding the same sponsor
organization/entity?**

No

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

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

Street address

Loghman Hakim Hospital, Kamali St, Makhsoos St

City

tehran

Province

Tehran

Postal code

1333635445

Phone

+98 21 5541 9005

Email

zahra.sahraei@yahoo.com

**Person responsible for scientific
inquiries**

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr. Zahra Sahraei

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

Street address

Loghman Hakim Hospital, Kamali St, Makhsoos St

City

tehran

Province

Tehran

Postal code

1333635445

Phone

+98 21 5541 9005

Email

zahra.sahraei@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Sareh Razzazzadeh

Position

resident

Latest degree

Medical doctor

Other areas of specialty/work

Medical Pharmacy

Street address

Valieasr St, Niyayesh Highway, Shahid Beheshti
University of Medical Sciences, School of Pharmacy

City

tehran

Province

Tehran

Postal code

1991953381

Phone

+98 21 8820 0118

Email

sareh3z@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is 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

Title and more details about the data/document

All potential data can be shared after blinding

When the data will become available and for how long

Six months after results published

To whom data/document is available

Researchers working in academic institutions

Under which criteria data/document could be used

For research purposes and meta analysis

From where data/document is obtainable

Dr. Zahra Sahraei, Loghman Hakim Hospital, Kamali St,
Makhsos St, Tehran

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

Official letter to the researchers

Comments