Clinical Trial Protocol
Iranian Registry of Clinical Trials

27 May 2026

Evaluation of vancomycin pharmacokinetics with two different regimens in patients with augmented renal clearance

Protocol summary

Study aim
Evaluation of Vancomycin Pharmacokinetics with Two Different Regimens in Patients with Augmented Renal Clearance

Design
Randomized clinical trial with parallel groups on 56 patients. Block randomization method will be used trough online website.

Settings and conduct
This study will be conducted in the Loghman Hakim hospital, Tehran. Patients with augmented renal clearance will be allocated into two groups randomly and vancomycin will be administered every 8 hours or every 12 hours. Finally, blood samples will be taken to measure peak and trough levels of vancomycin.

Participants/Inclusion and exclusion criteria
In this study, patients who needs vancomycin empirically or according to the culture will be included. These patients are over 18 years old and have augmented renal clearance (ARC) score between 7 and 10 or augmented renal clearance in trauma intensive care (ARCTIC) score over than 6. Patients with creatinine level lower than 1.5 mg/dL will be excluded. After initiation of intervention, the clearance of creatinine will be measured with collection of eight hours urine and patients with clearance of creatinine lower than 130 mL/minute will be excluded.

Intervention groups
In the first group, patients will be received intravenous vancomycin manufactured by Exir company at dose of 15 to 20 mg/kg every 12 hours. In the second group, patients will be received intravenous vancomycin manufactured by Exir pharmaceutical company at dose of 15 to 20 mg/kg every 8 hours. The infusion rate of vancomycin is 1000 mg per hour. One hour after ending the infusion of forth dose, blood sample will be taken to measure the peak level of vancomycin. Then, 30 minutes before administration of fifth dose blood sample will be taken to measure the trough level of vancomycin.

Main outcome variables
Ratio of patients who achieves Area under the curve (AUC)/Minimum inhibitory concentration (MIC) over 400.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20180802040665N1**
Registration date: **2021-02-20, 1399/12/02**
Registration timing: **prospective**

Last update: **2021-02-20, 1399/12/02**
Update count: **0**

Registration date
2021-02-20, 1399/12/02

Registrant information

Name
Ali Saffaei

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 21 7780 1199

Email address
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-04-04, 1400/01/15

Expected recruitment end date
2021-10-07, 1400/07/15

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of vancomycin pharmacokinetics with two different regimens in patients with augmented renal clearance

Public title

Evaluation of vancomycin pharmacokinetics in patients with augmented renal clearance

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age over 18 years old Need of vancomycin therapy with empirical approach or according to the culture Augmented renal clearance (ARC) score between 7 and 10 Augmented renal clearance in trauma intensive (ARCTIC) score over than 6 Signing the informed consent form

Exclusion criteria:

Blood creatinine level lower than 1.5 mg/dL Pregnant or breastfeeding patients Patients with history of vancomycin hypersensitivity Patients with history of vancomycin taking in the current course of hospitalization

Age

From **18 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **56**

Randomization (investigator's opinion)

Randomized

Randomization description

Block randomization method was used in this study. 14 blocks including 4 patients generated with online website. In each block, two patients will be assigned to group A (every 12 hours) and two patients will be assigned to group B (every 8 hours).

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

2021-02-14, 1399/11/26

Ethics committee reference number

IR.SBMU.PHARMACY.REC.1399.356

Health conditions studied

1

Description of health condition studied

Augmented renal clearance

ICD-10 code

R94.4

ICD-10 code description

Abnormal results of kidney function studies

Primary outcomes

1

Description

Ratio of patients with Area under the curve (AUC)/Minimum inhibitory concentration (MIC) over 400

Timepoint

Three days after initiation of intervention

Method of measurement

High performance liquid chromatography

Secondary outcomes

1

Description

Blood trough level of vancomycin

Timepoint

Three days after initiation of intervention

Method of measurement

High performance liquid chromatography

2

Description

Getting acute kidney injury

Timepoint

Seven days after initiation of intervention

Method of measurement

Measurement of creatinine blood level

Intervention groups

1

Description
Intervention group: patients will be received intravenous vancomycin manufactured by Exir pharmaceutical company at dose of 15 to 20 mg/kg every 12 hours. The infusion rate of vancomycin is 1000 mg per hour.
Category
Treatment - Drugs

2

Description
Intervention group: patients will be received intravenous vancomycin manufactured by Exir pharmaceutical company at dose of 15 to 20 mg/kg every 8 hours. The infusion rate of vancomycin is 1000 mg per hour.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Loghman Hakim hospital
Full name of responsible person
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
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3 rd floor, School of Medicine, Evin St, Shahid 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
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Assistant professor
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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
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 mounts 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 Valieasr St, Niyayesh Highway, Shahid Beheshti University of Medical Sciences, School of Pharmacy, 3rd floor, Department of Clinical Pharmacy Zip Code: 1996835113 Telephone: +982188200209 Email: z.sahraei@sbmu.ac.ir
What processes are involved for a request to access data/document
Official letter to the researchers, then after 7 days, their request will be answered.
Comments