

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Jul 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 through 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)

Phone

+98 21 7780 1199

Email address

saffaei@sbmu.ac.ir

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

Ilad Alavi Darazam

Street address

Loghman Hakim Hospital, Kamali St, Makhsoos St

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Tehran

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1333635445

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ilad13@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

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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

Zahra Sahraei

Position

Assistant professor

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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Full name of responsible person

Minoosh Shabani

Position

Assistant professor

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Other areas of specialty/work

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Person responsible for updating data**Contact****Name of organization / entity**

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Full name of responsible person

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Position

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Latest degree

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Other areas of specialty/work

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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 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 Valieasr St, Niyayesh Highway, Shahid Beheshti University of Medical Sciences, School of Pharmacy, 3rd floor, Department of Clinical Pharmacy
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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