Clinical Trial Protocol
Iranian Registry of Clinical Trials

19 Sep 2026

Comparison of pharmacokinetic parameters and clinical outcomes of vancomycin administered in two different dosage regimens in patients with acute kidney injury

Protocol summary

Study aim
Comparison of pharmacokinetic parameters of vancomycin administered in two different dosage regimens in patients with acute kidney injury and evaluationthe ratio of Area under the curve (AUC) / Minimum inhibitory concentration (MIC) more than 400 among each group.

Design
Randomized Clinical trial with two arm parallel group of 28 patients, phase 3 with the computer-generated random numbers method of randomization

Settings and conduct
This clinical trial suppose to run at Tehran, Loghman Hakim hospital on 28 patients who are receiving vancomycin for at least four doses and developed acute kidney injury will be divided into two group. control group will be received vancomycin 15-20 mg/kg every 12 hours without any adjustment. intervention group is supposed to received adjusted doses of vancomycin according to their creatinine and vancomycin clearance.

Participants/Inclusion and exclusion criteria
Patients over 18 years old with acute kidney injury who have received at least four doses of vancomycin will be included. pregnant or breastfeeding patients or those with history of chronic kidney disease or vancomycin allergy

Intervention groups
Patients who are receiving at least four doses of vancomycin as 15-20 mg/kg every 12 hours and developed acute kidney injury within treatment, could roll in the trial and then they will be allocated into two groups. fourteen patients in control group will be received full dos of vancomycin without any adjustment and the other fourteens patients in the intervention group supposed to received adjusted doses of vancomycin based on creatinine clearance and vancomycin clearance subsequently.

Main outcome variables
Percentage of patients who reach therapeutic level and AUC/MIC ≥ 400

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20130917014693N16**
Registration date: **2023-01-26, 1401/11/06**
Registration timing: **prospective**

Last update: **2023-01-26, 1401/11/06**
Update count: **0**

Registration date
2023-01-26, 1401/11/06

Registrant information
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Zahra Sahraei
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2023-03-20, 1401/12/29
Expected recruitment end date
2024-03-20, 1403/01/01

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of pharmacokinetic parameters and clinical outcomes of vancomycin administered in two different dosage regimens in patients with acute kidney injury

Public title
Evaluation of vancomycin dosing regimen in patients with acute kidney injury
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Receiving at least four doses of vancomycin Suffering from acute kidney injury according to KDIGO guideline while receiving vancomycin as said
Exclusion criteria:
Pregnant or breastfeeding Younger than 18 years old History of chronic kidney disease History of vancomycin allergy
Age
From **18 years** old
Gender
Both

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **28**
More than 1 sample in each individual
Number of samples in each individual: **3**
one blood sample on day one and two blood sample on forth day
Randomization (investigator's opinion)
Randomized
Randomization description
Simple randomization. patients are placed in to two control and intervention groups using a table of random numbers in a ratio of 1:1. To use the table of random numbers, a column and a row are randomly selected, and the 2 digits on the left side of the crossing point is the first selected number. A hypothetical plus is drawn from that number and the numbers placed in that plus are selected. This process continues until half of the total number of samples is selected, and this numbers will determine the intervention group
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 Science
Street address
3rd floor, school of medicine, Evin St, Shahid Chamran highway
City
Tehran
Province
Tehran
Postal code
1983963113
Approval date
2022-10-25, 1401/08/03
Ethics committee reference number
IR.SBMU.PHARMACY.REC.1401.140

Health conditions studied

1

Description of health condition studied
Acute kidney injury
ICD-10 code
N17.9
ICD-10 code description
Acute renal failure, unspecified

Primary outcomes

1

Description
Percentage of patients who reach therapeutic target of Area under the curve (AUC)/Minimum inhibitory concentration (MIC) over 400.
Timepoint
First and forth day of study
Method of measurement
measuring plasma level of vancomycin with ECL Immunoassay method

Secondary outcomes

1

Description
Clinical condition improvement like the rate of fever or mortality
Timepoint
daily
Method of measurement
observation

Intervention groups

1

Description
Control group: patients in this group will be received Vancomycin with the dose of 15-20 mg/kg every 12 hour over 60 minute infusion as empiric or targeted therapy.
Category
Treatment - Drugs

2

Description
Intervention group: patients in this group will be received adjusted dose of vancomycin based on creatinine clearance (Cockcroft-Gault equation). patients with creatinine clearance 5 to 50 milliliter/minute will receive 10 to 15 milligram/kilogram daily and patients with creatinine clearance less than 25 milliliter/minute will receive 10 to 15 milligram/kilogram every 48 hours. These patients will be visited everyday to make sure they've been received corrected and daily adjusted doses of vancomycin. creatinine clearance= [140 - age(years)] / 72cr. the calculated creatinine clearance should be multiplied by 0.85 if female.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Loghman Hakim Hospital
Full name of responsible person
Zahra Sahraei
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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
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
Associated professor
Latest degree
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Other areas of specialty/work
Medical Pharmacy
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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
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
academic institution's researchers

Under which criteria data/document could be used
research purposes and meta-analysis

From where data/document is obtainable
Dr. Zahra Sahraei, Loghman Hakim Hospital, Kamali St, Makhsoos St, Tehran

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

Comments