

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 evaluation the 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

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

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

AgeFrom **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= $\frac{[140 - \text{age}(\text{years})]}{72 \times \text{cr}}$. 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

Street address

South Kargar St, Makhsous 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@sbmu.ac.ir

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

Ph.D.

Other areas of specialty/work

Medical Pharmacy

Street address

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

City

Tehran

Province

Tehran

Postal code

1996835113

Phone

+98 21 8887 3704

Email

z.sahraei@sbmu.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Zahra Sahraei

Position

Associate professor

Latest degree

Ph.D.

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

1996835113

Phone

+98 21 8887 3704

Email

z.sahraei@sbmu.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

rokhsareh soufi

Position

resident

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

Street address

Vali-e Asr Ave., Niayesh junction

City

Tehran

Province

Tehran

Postal code

1996835113

Phone

+98 21 8887 3704

Fax

+98 21 8887 3704

Email

rokhsareh_soufi@yahoo.com

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 months 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,
Makhsos St, Tehran

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

official letter to researchers

Comments