

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 Jun 2026

Comparison of Vancomycin Area Under the Curve (AUC) in Continuous and Intermittent Infusion Regimens in Pediatric Patients Admitted to the Intensive Care Unit

Protocol summary

Study aim

Comparison of Vancomycin Area Under the Curve (AUC) in Continuous and Intermittent Infusion Regimens in Pediatric Patients Admitted to the Intensive Care Unit

Design

A randomized, blinded, and controlled phase three clinical trial with a parallel-group design of 72 patients; Randomisation was centralised and computerised with block randomisation sequence carried out at an sealed envelope.com site.

Settings and conduct

Place of study: A Tertiary Teaching Children's Hospital
How to do the study: Seventy-two patients who are candidates for vancomycin therapy are randomly divided into intervention or control groups. Investigator, outcome assessor and data analyzer are blind to the study groups until the end of the study

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age 2 months to 15 years old, weight under 67 kg, central venous access, obtaining written consent from a legal guardian
Exclusion criteria: Renal impairment, GFR<50 ml/min (Schwartz formula), required extracorporeal membrane oxygenation or plasmapheresis, discontinuation of vancomycin before 3 days after administration due to clinical judgment

Intervention groups

Intervention group: Vancomycin will be received as a loading dose of 15mg/kg and a continuous infusion of 60mg/kg over 24 hours. The Control group will receive vancomycin as an intermittent infusion of 15mg/kg every 6 hours.

Main outcome variables

Vancomycin area under the curve (AUC)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120415009475N12**

Registration date: **2022-07-05, 1401/04/14**

Registration timing: **prospective**

Last update: **2022-07-05, 1401/04/14**

Update count: **0**

Registration date

2022-07-05, 1401/04/14

Registrant information

Name

Bahador Mirrahimi

Name of organization / entity

Shahid Beheshti University of Medical Sciences,
Faculty of Pharmacy

Country

Iran (Islamic Republic of)

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+98 21 8820 0118

Email address

mirrahimi@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-08-23, 1401/06/01

Expected recruitment end date

2024-08-22, 1403/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of Vancomycin Area Under the Curve (AUC) in Continuous and Intermittent Infusion Regimens in Pediatric Patients Admitted to the Intensive Care Unit

Public title

Comparison of continuous and intermittent infusion administration methods of Vancomycin

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Age 2 months to 15 years old Weight under 67 kg Central venous access Obtaining written consent from a legal guardian

Exclusion criteria:

Renal impairment, GFR<50 ml/min (Schwartz formula) Need for hemodialysis or CRRT Need for extracorporeal membrane oxygenation or plasmapheresis Loss of Central venous access Lysis of blood samples Discontinuation of vancomycin before 3 days of administration due to clinical judgment Retraction of consent by legal guardian

Age

From **2 months** old to **15 years** old

Gender

Both

Phase

3

Groups that have been masked

- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **72**

More than 1 sample in each individual

Number of samples in each individual: **2**

Two separate blood samples will be taken from the patient at different times within 24 hours

Randomization (investigator's opinion)

Randomized

Randomization description

The Block randomization method will be used in this study. Eighteen blocks including four patients will be generated with the online website (www.sealedenvelope.com/simple-randomiser/v1). In each block, two patients will be randomly assigned to the continuous infusion group and two patients will be assigned to the intermittent infusion group.

Blinding (investigator's opinion)

Double blinded

Blinding description

The patient data will be in coded same packages; a designated person will provide the codes from permuted block randomization via phone. The same person will group the data at the end of the trial, and the expert will perform statistical analysis. After the results, the pocket with the randomization provider will be opened, and the data will be decrypted. The data regarding the harm and benefits of treatment groups will be provided to the

patient and caregiver.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Schools of Pharmacy, Nursing and Midwifery Shahid Beheshti University of Medic

Street address

2nd floor, School of Nursing and Midwifery, Valiasr and Niayesh junction

City

Tehran

Province

Tehran

Postal code

1546815514

Approval date

2022-01-25, 1400/11/05

Ethics committee reference number

IR.SBMU.PHARMACY.REC.1400.293

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

Proven or suspected Infection with methicillin resistant staphylococcus aureus candidate for Vancomycin Treatment

ICD-10 code

A49.02

ICD-10 code description

Methicillin resistant Staphylococcus aureus infection, unspecified site

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

Serum level of vancomycin

Timepoint

Third day of receiving vancomycin

Method of measurement

Fluorescence Polarization Immunoassays

Secondary outcomes

1

Description

Clinical response

Timepoint

5 Days

Method of measurement

Use the Pediatric Sequential Organ Failure Assessment score and Pediatric Risk of Mortality III score to predict mortality in the pediatric intensive care unit

2

Description

Duration of ICU stay

Timepoint

1 Month

Method of measurement

Day

Intervention groups

1

Description

Intervention group: Vancomycin will be given as a loading dose of 15 mg/kg followed by a continuous infusion of 60 mg/kg over 24 hours

Category

Treatment - Drugs

2

Description

Control group: Vancomycin will be given at a dose of 15 mg/kg every 6 hours.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Mofid Children's Hospital

Full name of responsible person

Bahador Mirrahimi

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Mofid Children's Hospital, Mirdamad Junction, Shariaty Ave.,

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mirrahimi@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr. Seyed Ali Ziaee

Street address

3rd Floor, Faculty of medicine, Arabi Ave, Daneshjoo Blvd, Velenjak

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1985717443

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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

Baran roshan

Position

Clinical Pharmacy Resident

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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Position

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Latest degree

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Other areas of specialty/work

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Person responsible for updating data

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Latest degree

Specialist

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

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

The main outcome will be available

When the data will become available and for how long

Six months after publishing

To whom data/document is available

The data will be available per request for people working in academic institutions

Under which criteria data/document could be used

The data will available for using in systematic review and meta-analysis

From where data/document is obtainable

The data will be available by contacting email; mirrahimi@sbmu.ac.ir

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

The data will available for using in systematic review and meta-analysis

Comments