

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Evaluating effect of optimizing vancomycin dosing according to AUC/MIC on systemic inflammatory responses syndrome (SIRS) in septic patients

Protocol summary

Study aim

Comparing effect of two methods of vancomycin dosing on clearance of systemic inflammatory responses in septic patients

Design

This is a open-label randomized clinical trial. Forty adults with diagnosis of sepsis will equally be assigned to intervention or control group according permuted block randomization method.

Settings and conduct

Critically ill adult patients with diagnosis of sepsis and augmented renal clearance who admitted to general ICU of Imam Khomeini Hospital will be evaluated for eligibility. Forty patients will equally be assigned to intervention or control group according the permuted block randomization method. Vancomycin dose in patients in the intervention group will be calculated according to AUC/MIC index. In patients in the control group vancomycin dose will be calculated according to the serum trough concentration. Duration of intervention is 5 days.

Participants/Inclusion and exclusion criteria

Patients with sepsis older than 18 years of age who have augmented renal clearance will be included in this study

Intervention groups

Vancomycin dose in this group will be calculated using AUC/MIC index. Vancomycin AUC will be assumed based on the vancomycin peak and trough serum concentrations. MIC value will be considered 1.5 mg/l (attained from local data)

Main outcome variables

Attaining serum target concentration, clearance of systemic inflammatory responses and vancomycin renal safety are main outcomes. Target of vancomycin dose in the intervention group is $AUC/MIC \geq 400$ and in the control group is serum trough level of 15-20 mg/l.

General information

Reason for update

Acronym

VIA

IRCT registration information

IRCT registration number: **IRCT20100228003449N24**

Registration date: **2018-07-21, 1397/04/30**

Registration timing: **prospective**

Last update: **2018-07-21, 1397/04/30**

Update count: **0**

Registration date

2018-07-21, 1397/04/30

Registrant information

Name

Hossein Khalili

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 21 6695 4715

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khalilih@tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-07-23, 1397/05/01

Expected recruitment end date

2019-07-23, 1398/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluating effect of optimizing vancomycin dosing according to AUC/MIC on systemic inflammatory responses syndrome (SIRS) in septic patients

Public title

Optimizing vancomycin dosing in septic patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with sepsis Patients with augmented renal clearance Patients with vancomycin indication Serum creatinine less than 1.3 mg/dl

Exclusion criteria:

Age less than 18 years old and more than 75 years old Receiving concomitant nephrotoxic agents Pregnancy Patients with vancomycin contraindications

Age

From **18 years** old to **75 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization unit: Block randomization Randomization tool: SAS statistical software, sealed envelope How to create a random sequence: SAS statistical software

Blinding (investigator's opinion)

Not blinded

Blinding description

Use non-transparent sealed envelopes with random sequences

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Tehran University Of Medical Sciences

Street address

Ghods Ave. Tehran University of Medical Sciences, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

-

Approval date

2018-07-05, 1397/04/14

Ethics committee reference number

IR.TUMS.TIPS.REC.1397.007

Health conditions studied

1

Description of health condition studied

Sepsis

ICD-10 code

A41.9

ICD-10 code description

Sepsis, unspecified

Primary outcomes

1

Description

Access vancomycin target concentration

Timepoint

Days 2-5

Method of measurement

Chemiluminescent immunoassay (CLIA)

2

Description

Clearance of systemic inflammatory response syndrome

Timepoint

Daily

Method of measurement

Evaluating vital signs, hemodynamic parameters and laboratory tests

Secondary outcomes

1

Description

Vancomycin induced nephrotoxicity

Timepoint

Daily measurement of serum creatinine

Method of measurement

0.5 mg/dl or 50% increase in serum creatinine from the baseline value

Intervention groups

1

Description

Vancomycin dosing according to AUC/MIC index

Category

Treatment - Drugs

2

Description

Vancomycin dosing according to serum trough level

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam khomeini hospital complex

Full name of responsible person

Hossein khalili afousi

Street address

Keshavarz Blvd

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Mohammad Ali Sahraian

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Vice Chancellor for Research, Tehran University of Medical Sciences, Ghods Ave., Tehran, Iran

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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

Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

Hossein khalili afousi

Position

Professor

Latest degree

Specialist

Other areas of specialty/work

Pharmacotherapy

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be 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

Undecided - It is not yet known if there will be 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

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

Results of the study will be published. The study protocol and statistical analysis will be included in the manuscript.

When the data will become available and for how long

One year after end of the study, data will be published and will be available in databases.

To whom data/document is available

After permission from the sponsor, data of the study will be available for academic researchers, physicians and scientific institutes.

Under which criteria data/document could be used

Other researchers are permitted to include the results in their systematic reviews and meta-analysis.

From where data/document is obtainable

Contact scientific responsible person for the clinical trial as needed

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

After receiving the query, dependent on the requested data, the scientific responsible person of the study will respond to the query in coordinate with the sponsor within 2 weeks.

Comments

Data sharing is according to permission from the sponsor.