Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Nov 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>=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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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 Scienses

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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msahrai@sina.tums.ac.ir
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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Person responsible for updating data

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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 form 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 included 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 response to the query in coordinate with the sponsor within 2 weeks.
Comments
Data sharing is according to permission from the sponsor.