Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Dec 2021

Comparison of fixed and individualized regimen of vancomycin in achievement to recommended blood concentration based on clinical guidelines in critically ill patients.

Protocol summary

Summary

Objective: The aims of this study are to evaluation of vancomycin dosing in critically ill patients and comparison with standard treatment guidelines for rational prescribing of medicine. Design: Critically ill patients (N=64) who received vancomycin during their treatment course will be randomized in two groups. Setting and conduct: This study will be performed in two phases. In the first phase, serum concentrations of vancomycin will be measured without any intervention and pharmacokinetic parameters of patients will be calculated. In the second phase, patients will be randomized in two groups. One of the groups will be received fixed dose of vancomycin and in the other one, the dose will be individualized based on serum concentrations. Participants: Critically ill patients with evidence of sepsis, survival prognosis > 72 hours and Glomerular filtration rate (GFR) > 60 ml/min will be enrolled to the study. Acute renal failure, adverse drug reaction and discontinuation of vancomycin within 72 hours are the major exclusion criteria. Intervention: After administration of vancomycin, serum concentrations of vancomycin will be measured at different points and dosage will be adjusted and individualized. Main outcome measures: Peak and trough concentration of vancomycin in critically ill patients, Comparison of dosing with standard treatment guidelines, Correlation of different variables such as Serum creatinin and mechanical ventilation to pharmacokinetic parameters of vancomycin.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201209291497N2**
Registration date: **2012-10-26, 1391/08/05**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2012-10-26, 1391/08/05

Registrant information

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Recruitment status

Recruitment complete

Funding source

Vice chancellor of research, Tehran University of Medical Sciences

Expected recruitment start date

2012-10-22, 1391/08/01

Expected recruitment end date

2014-06-22, 1393/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of fixed and individualized regimen of

vancomycin in achievement to recommended blood concentration based on clinical guidelines in critically ill patients.

Public title
Adjustment of vancomycin dosage in critically ill patients.
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria: Age over 18 years, Glomerular Filtration Rate (GFR) > 60 ml/min, evidence of sepsis, survival prognosis> 72 hours, the lack of sensitivity to the drug, drug administration in past 72 hours. Exclusion criteria: Patient death within 72 hours of the beginning of the study, acute renal failure during the study (according to the criteria of RIFLE), adverse drug reaction, change of treatment during the first 72 hours of treatment, discontinuation of drug during the first 72 hours of treatment, the loss of the samples of the first 48 hours, no individualization during the initial 48 hours of treatment.
Age
From **18 years** old to **70 years** old
Gender
Both

Phase
1-2
Groups that have been masked
No information
Sample size
Target sample size: **64**
Randomization (investigator's opinion)
Randomized
Randomization description
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
Ethic Committee of Tehran University of Medical Sciences
Street address
Fourth floor, Central Organization of Tehran University of Medical Sciences, Corner of Ghods Street, Keshavarz Blvd.
City
Tehran
Postal code
Approval date
2012-09-23, 1391/07/02
Ethics committee reference number
91-02-156-18212-65308

Health conditions studied

1

Description of health condition studied
sepsis
ICD-10 code
A41.0
ICD-10 code description
Sepsis due to Staphylococcus aureus

Primary outcomes

1

Description
Cumulative dose
Timepoint
First 72 hours of treatment
Method of measurement
sum of the used dose based on patient chart

2

Description
Maximum concentration of drug in steady state
Timepoint
After at least 3 half- life, or changing the dose
Method of measurement
ELISA KIT

3

Description
Minimum concentration of drug in steady state
Timepoint
After at least 3 half- life, or changing the dose
Method of measurement
ELISA KIT

4

Description
Mean of the intervention for dose adjustment
Timepoint
Number of dose adjustment based on pharmacokinetic data
Method of measurement
Evaluation of recorded intervention on patient's chart

Secondary outcomes

1

Description
Positive Expiratory End Pressure(PEEP)
Timepoint

Each time patient received vancomycin

Method of measurement

Patient chart

2

Description

Tidal volume

Timepoint

Each time patient received vancomycin

Method of measurement

Patient chart

3

Description

Serum creatinin

Timepoint

Each time patient received vancomycin

Method of measurement

Patient chart

4

Description

Mean Arterial Pressure

Timepoint

Each time patient received vancomycin

Method of measurement

Patient chart

5

Description

Urine Output

Timepoint

Each time patient received vancomycin

Method of measurement

Patient chart

Intervention groups

1

Description

In the first phase, due to the uncertainty constant serum concentrations of fixed dose regimen -in patients who have indications for treatment with vancomycin- serum concentrations of vancomycin for 4 consecutive first dose, with loading dose of 25mg/kg and then 15 mg/kg/dose every 12 hours will be measured without any intervention. Pharmacokinetic parameters of patients will be calculated. After ensuring the patient's kinetic parameters, the second phase of the study will be conducted.

Category

Treatment - Drugs

2

Description

Phase 2: At this stage, patients are divided randomly (block randomization based on block size 4) into two groups. The first group of patients will be treated using a fixed-dose protocol of 25mg/kg/stat then 15mg/kg/dose every 12 hours and then serum concentrations will be evaluated at 8 times: 1- end of infusion of first dose 2- second dose trough 3- third dose trough 4- fourth dose trough 5- fifth dose trough 6- sixth dose trough 7- eleventh dose trough 8- trough at 15 dose. In second group, vancomycin will be administered with a loading dose of 25mg/kg/stat and then will be individualized. Drug concentration will be measured at 9 times: 1- end of infusion of first dose 2- second dose trough 3- third dose trough 4- second dose peak 5- 6-8 hours after third dose 6- third dose trough 7- fourth dose trough 8- sixth dose trough 9- seventh dose trough. And then treatment will be continued based on fixed dose protocol and physician order.

Category

Treatment - Drugs

3

Description

Patients who have the inclusion criteria will be enrolled to the study and received vancomycin (Jaber Ebne Hayyan Pharmaceutical Co., Tehran, Iran) through Intravenous infusion (at least 1 hour), with loading dose of 25mg/kg and then 15 mg/kg/dose every 12 hours. Depending on the phase of study, serum concentrations will be evaluated and vancomycin dosage will be adjusted. Patients will be followed up for 7 days and vancomycin dosage will be individualized for them.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Sina Hospital

Full name of responsible person

Sarah Mousavi

Street address

5th Floor,No. 92, Karimkhan Street, Hafte- Tir Square

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Tehran University of Medical Sciences

Full name of responsible person

Dr Akbar Fotouhi

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Fourth floor, Central Organization of Tehran University of Medical Sciences, Corner of Ghods Street, Keshavarz Blvd.

City
Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice chancellor for research, Tehran University of Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty