

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

Name

Sarah Mousavi

Name of organization / entity

Clinical Pharmacy Department, Pharmacy Faculty,
Isfahan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 31 3792 2567

Email address

smousavi@razi.tums.ac.ir

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, Haft- 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

Street address

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

Contact

Name of organization / entity
Clinical Pharmacy Department, School of Pharmacy,
Tehran University of Medical Sciences

Full name of responsible person
Dr Farhad Najmedin

Position
Resident of Clinical Pharmacy

Other areas of specialty/work

Street address
5th floor, No. 92, Karimkhan Street, Haft-Tir Square

City
Tehran

Postal code

Phone
+98 21 8881 4158

Fax

Email
Farhad.najm@gmail.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity
Clinical Pharmacy Department, School of Pharmacy,
Tehran University of Medical Sciences

Full name of responsible person
Dr Mojtaba Mojtahedzadeh

Position

Professor of Clinical Pharmacy

Other areas of specialty/work

Street address
2nd floor, Old building, Pharmacy Faculty, 16th Azar Ave., Keshavarz Blvd., Pharmacotherapy Dep.

City
Tehran

Postal code

Phone
+98 21 8881 4157

Fax

Email
mojtahed@sina.tums.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity
School of Pharmacy, Tehran University of Medical Sciences

Full name of responsible person
Bitah Shahrami

Position
Pharmacy Student

Other areas of specialty/work

Street address
2nd floor, Old building, Pharmacy Faculty, 16th Azar Ave., Keshavarz Blvd., Pharmacotherapy Dep.

City
Tehran

Postal code

Phone
+98 21 8881 4158

Fax

Email
bita.shahrami@gmail.com

Web page address

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