Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparison of the different doses of vancomycin on plasma concentration of the drug in patients hospitalized in ICU: a double blind randomized clinical trial

Protocol summary

Summary

Objectives: To assess the effect of different doses of vancomycin on plasma concentration of the drug in patients hospitalized in ICU. Design: A double blind randomized clinical trial. Setting and conduct: The eligible patients who need to hospitalize in ICU wards and will refer to Sina Hospital during the study period will be enrolled into the trial. Inclusion criteria: Age of 18 to 60 years; meningitis or endocarditis or sepsis or osteomyelitis with positive culture for staph or enterococci resistant to methicillin. Exclusion criteria: Hypersensitivity to vancomycin; renal toxicity; using aminoglycoside drugs concurrently. Intervention group 1: First injection of 1 g vancomycin as single dose and then 2 g per day for 2 weeks. Intervention group 2: First injection of 1 gr vancomycin as single dose and then 15 mg/kg per day for 2 weeks. Primary outcome: Measuring plasma concentration of vancomycin through High Performance Liquid Chromatography 2 months after treatment. Randomization: / Random assignment of the patients to the intervention and control groups through drawing of lot. Blinding: Patients will be unaware of the type of intervention. The physician who will examine the patients will not be aware of the intervention. Therefore, the trial will be run as double blind.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201710109014N194**
Registration date: **2017-10-12, 1396/07/20**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2017-10-12, 1396/07/20

Registrant information

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Name of organization / entity
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Recruitment status

Recruitment complete

Funding source

Vice-chancellor for Research and Technology, Hamadan University of Medical Sciences

Expected recruitment start date
2017-10-23, 1396/08/01
Expected recruitment end date
2018-03-16, 1396/12/25
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title

Comparison of the different doses of vancomycin on plasma concentration of the drug in patients hospitalized in ICU: a double blind randomized clinical trial

Public title

Comparison of the different doses of vancomycin on plasma concentration of the drug in patients hospitalized

in ICU

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Age of 18 to 60 years; meningitis or endocarditis or sepsis or osteomyelitis with positive culture for staph or enterococci resistant to methicillin. Exclusion criteria: Hypersensitivity to vancomycin; renal toxicity; using aminoglycoside drugs concurrently.

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Randomization: / Random assignment of the patients to the intervention and control groups through drawing of lot. Blinding: Patients will be unaware of the type of intervention. The physician who will examine the patients will not be aware of the intervention. Therefore, the trial will be run as double blind.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Hamadan University of Medical Sciences

Street address

Vice-chancellor for Research the Technology, Hamadan University of Medical Sciences, Shahid Fahmideh Ave

City

Hamadan

Postal code

Approval date

2017-05-13, 1396/02/23

Ethics committee reference number

IR.UMSHA.REC.1396.88

Health conditions studied

1

Description of health condition studied

Meningitis

ICD-10 code

G00

ICD-10 code description

Bacterial meningitis, not elsewhere classified

2

Description of health condition studied

Endocarditis

ICD-10 code

I33

ICD-10 code description

Acute and subacute endocarditis

3

Description of health condition studied

Sepsis

ICD-10 code

A41.9

ICD-10 code description

Sepsis, unspecified

4

Description of health condition studied

Osteomyelitis

ICD-10 code

M86

ICD-10 code description

Osteomyelitis

Primary outcomes

1

Description

Measuring plasma concentration of vancomycin

Timepoint

2 months after treatment

Method of measurement

Through High Performance Liquid Chromatography

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: First injection of 1 g vancomycin as single dose and then 2 g per day for 2 weeks.

Category

Treatment - Drugs

2

Description
Intervention group 2: First injection of 1 gr vancomycin as single dose and then 15 mg/kg per day for 2 weeks.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Sina Hospital
Full name of responsible person
Mohammadali Salahshoor
Street address
Sina Hospital, Mirzadeh Eshghi Ave.
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice-chancellor for Research and Technology, Hamadan University of Medical Sciences
Full name of responsible person
Dr Saeid Bashirian
Street address
Hamadan University of Medical Sciences, Shahid Fahmideh Ave
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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
Vice-chancellor for Research and Technology, Hamadan 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
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Person responsible for updating data

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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