

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 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

Name

Jalal Poorolajal

Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 81 1838 0090

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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.

City

Hamadan

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

City

Hamadan

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

Name of organization / entity

School of Pharmacy

Full name of responsible person

Mohammadali Salahshoor

Position

Student of Pharmacology

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

Name of organization / entity

School of Pharmacy

Full name of responsible person

Dr Katayoon Derakhshandeh

Position

Pharmacist

Other areas of specialty/work

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Web page address

Person responsible for updating data

Contact

Name of organization / entity

Department of Epidemiology

Full name of responsible person

Dr Jalal Poorolajal

Position

Associate Professor

Other areas of specialty/work

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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