

# 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

###### Email address

poorolajal@umsha.ac.ir

##### 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

##### Street address

School of Pharmacy, Hamadan University of Medical  
Sciences, Shahid Fahmideh Ave.

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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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## 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

##### Street address

School of Public Health, Hamadan University of  
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**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*