

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

30 Jun 2026

### Comparison of conventional vancomycin regimen (15mg/kg q12h) vs. high dose regimen (15mg/kg q8h) in acute bacterial meningitis patients

#### Protocol summary

##### Summary

the main goal of this study is comparison of high dose regimen of vancomycin with conventional regimen in acute bacterial meningitis and its specific goal is evaluating safety and efficacy of high dose regimen of vancomycin. Inclusion criteria: Filling consent form Patients with diagnosis of acute bacterial meningitis who are candidates for receiving vancomycin Age  $\geq 18$  yrs Not receive vancomycin in last 2 weeks Exclusion criteria: Clinical states which could change pharmacokinetic of vancomycin (eg. burn, cystic fibrosis, edema) Pregnancy Patients with CKD who need dialysis Contraindication for vancomycin this study is a randomized controlled clinical trial which 40 patients with diagnosis of acute bacterial meningitis who have indication for receiving vancomycin included in it. they will be divided in two 20 patients group, that first group will receive vancomycin with conventional dose (1000mg q12hr) and second group will receive it in high dose (1000mg q8hrs) in 1 hour infusion. all patients will be evaluated during the study for clinical response on basis of laboratory parameters (CBC & LP findings), physiologic and clinical neurologic examination. at the beginning of study and every other day 10cc blood sample will be drawn from all of the patients for evaluating the level of creatinine, KIM-1 and Cystatin-C. after infusion of third dose of vancomycin and in 10th day of therapy before morning dose, blood sample for measurement of serum trough level of vancomycin will be drawn. serum level of acute kidney injury biomarkers and vancomycin will be measured with ELISA kits and immunoassay methods.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201107233449N7**

Registration date: **2011-08-08, 1390/05/17**

Registration timing: **prospective**

Last update:

Update count: **0**

##### Registration date

2011-08-08, 1390/05/17

##### Registrant information

###### Name

Hossein Khalili

###### Name of organization / entity

Tehran University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 6695 4715

###### Email address

khalilih@tums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Tehran University of Medical Science (pharmacy faculty)

##### Expected recruitment start date

2011-09-23, 1390/07/01

##### Expected recruitment end date

2013-03-19, 1391/12/29

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparison of conventional vancomycin regimen (15mg/kg q12h) vs. high dose regimen (15mg/kg q8h) in acute bacterial meningitis patients

##### Public title

application of high dose regimen of vancomycin in acute bacterial meningitis

##### Purpose

Treatment

### **Inclusion/Exclusion criteria**

Inclusion criteria: Filling consent form; Patients with diagnosis of acute bacterial meningitis who are candidates for receiving vancomycin; Age  $\geq 18$  yrs; Not receive vancomycin in last 2 weeks Exclusion criteria: Clinical states which could change pharmacokinetic of vancomycin (eg. burn, cystic fibrosis, edema); Pregnancy; Patients with CKD who need dialysis ; Contraindication for vancomycin

### **Age**

From **18 years** old to **70 years** old

### **Gender**

Both

### **Phase**

N/A

### **Groups that have been masked**

*No information*

### **Sample size**

Target sample size: **40**

### **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**

Tehran University of Medical Sciences

##### **Street address**

Keshavarz Blvd., Tehran University of Medical sciences, Central organization, 6th Floor

##### **City**

Tehran

##### **Postal code**

#### **Approval date**

2011-07-23, 1390/05/01

#### **Ethics committee reference number**

90-02-33-13767

## **Health conditions studied**

### 1

#### **Description of health condition studied**

meningitis

#### **ICD-10 code**

G00

### **ICD-10 code description**

Bacterial meningitis, not elsewhere classified

## **Primary outcomes**

### 1

#### **Description**

serum level of Cystatin-C

#### **Timepoint**

every other day

#### **Method of measurement**

mg/l

### 2

#### **Description**

serum level of creatinine

#### **Timepoint**

every other day

#### **Method of measurement**

mg/dl

### 3

#### **Description**

serum level of KIM-1

#### **Timepoint**

every other day

#### **Method of measurement**

pg/ml

### 4

#### **Description**

serum level of vancomycin

#### **Timepoint**

third and 10th day

#### **Method of measurement**

mcg/ml

## **Secondary outcomes**

empty

## **Intervention groups**

### 1

#### **Description**

control group, vancomycin 1000mg q12hrs

#### **Category**

Treatment - Drugs

### 2

#### **Description**

intervention group, vancomycin 1000mg q8hrs 1hr infusion

#### **Category**

Treatment - Drugs

## Recruitment centers

1

### Recruitment center

**Name of recruitment center**

Imam Khomeini hospital

**Full name of responsible person**

**Street address**

**City**

Tehran

## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Fatemeh Shahidi

**Street address**

Enghelab Squire, Tehran University of Medical Sciences

**City**

Tehran

**Grant name**

**Grant code / Reference number**

**Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

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

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Hossein Khalili

**Position**

PharmD, BCPS, Associate Professor

**Other areas of specialty/work**

**Street address**

Department of Clinical Pharmacy (Pharmacotherapy), Pharmacy Faculty, Tehran University of Medical Sciences

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## Person responsible for updating data

### Contact

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Sepideh Elyasi

**Position**

PharmD, Resident of Clinical Pharmacy

**Other areas of specialty/work**

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Department of Clinical Pharmacy (Pharmacotherapy), Pharmacy Faculty, Tehran University of Medical Sciences

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**Postal code**

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**Fax**

**Email**

**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*