

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 ≥ 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 1hour 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 ≥ 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

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Person responsible for updating data

Contact

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Full name of responsible person

Sepideh Elyasi

Position

PharmD, Resident of Clinical Pharmacy

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