

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of effect of administration of vancomycin by continuous infusion versus intermittent infusion on concentration of vancomycin in the CSF in postneurosurgical meningitis patients

Protocol summary

Summary

Aim of study: Determine an appropriate therapeutic regimen for postneurosurgical meningitis patients in order to achieve desired vancomycin concentration in CSF. Study design: random; without placebo; single center; Method: Population of study: patients with postneurosurgical meningitis; Inclusion criteria: Patients who diagnosed postneurosurgical meningitis and received vancomycin; Age>18 years old; Exclusion criteria: Chronic kidney disease (creatinine clearance<50 mL/min) before initiate treatment; Occurring of acute kidney disease (according to the AKIN); Administration of intrathecal vancomycin; Through level<15mcg/mL; Through level>30mcg/mL; Sample volume: 20 patient Intervention: infusion of high dose of vancomycin in two methods: intermittent infusion and continuous infusion; Time of intervention: 21 days; from start of treatment till end of it; Result: vancomycin concentration in CSF; vancomycin concentration in serum; treatment efficacy. Method: 20 patients distribute in two equal groups randomly. In one group, at first, 10 patients will receive loading dose of 30 mg/kg then maintenance dose of 25 mg/kg twice daily by intermittent infusion. In another group, at first, 10 patients will receive loading dose of 30 mg/kg then maintenance dose of 50 mg/kg by continuous infusion. In addition, both groups will receive meropenem (2g IV TDS) and dexamethasone (10 mg IV QID) as conventional treatment.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016071114693N6**
Registration date: **2016-10-08, 1395/07/17**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-10-08, 1395/07/17

Registrant information

Name

Zahra Sahraei

Name of organization / entity

Faculty of pharmacy, Shahid beheshti university of medical sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 8887 3704

Email address

z.sahraei@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Shahid Beheshti University of Medical Sciences

Expected recruitment start date

2015-08-23, 1394/06/01

Expected recruitment end date

2016-12-20, 1395/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of effect of administration of vancomycin by continuous infusion versus intermittent infusion on concentration of vancomycin in the CSF in postneurosurgical meningitis patients

Public title

Vancomycin dosing in treatment of meningitis

Purpose

Treatment

Inclusion/Exclusion criteria

(Inclusion criteria: patients who diagnosed postneurosurgical meningitis and received vancomycin; Age>18 years old) (Exclusion criteria: chronic kidney disease (creatinine clearance<50 mL/min) before initiate threatment; occurring of acute kidney disease (according to the AKIN); administration of intrathecal vancomycin; through level<15mcg/mL; through level>30mcg/mL)

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **20**

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**

Shahid Beheshti University of Medical Sciences

Street address

tehran- velengak- shahid beheshti university of medical sciences

City

tehran

Postal code**Approval date**

2015-09-29, 1394/07/07

Ethics committee reference number

SBMU2.REC.1394.128

Health conditions studied**1****Description of health condition studied**

postneurosurgical meningitis

ICD-10 code

G00.1, G00

ICD-10 code description

Pneumococcal meningitis, Streptococcal meningitis

Primary outcomes**1****Description**

CSF vancomycin concentration

Timepoint

day 3 and day 5 of treatment

Method of measurement

mcg/mL, Fluorescent PolarizationImmunoassay, by Cobas system

2**Description**

serum concentration of vancomycin

Timepoint

day 3 and 5 of treatment

Method of measurement

mcg/mL, Fluorescent PolarizationImmunoassay, by Cobas system

Secondary outcomes

empty

Intervention groups**1****Description**

vancomycin, 25 mg/kg Q12H, intermittent infusion, twice daily, for 21 days

Category

Treatment - Drugs

2**Description**

vancomycin, 50mg/kg, continuous infusion, for 21 days

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Loghman Hakim Hospital

Full name of responsible person

Dr. Sahraee Zahra, Board Certified Pharmacotherapy Specialists

Street address

Loghman Hakim Hospital, Makhsoos St, South Karegar Ave, Tehran, Iran

City
Tehran

Phone
+98 21 2243 9770

Fax

Email
morteza.taheri83@yahoo.com

Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Dr. Nima Naderi

Street address
Shahid Beheshti University of Medical Sciences, Arabi
Ave, Daneshjoo Blvd, Velenjak, Tehran, Iran

City
Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source
Shahid Beheshti 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
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Dr. Taheri Morteza

Position
Resident of Pharmacotherapy

Other areas of specialty/work

Street address
Shahid Beheshti University of Medical Sciences, Arabi
Ave, Daneshjoo Blvd, Velenjak, Tehran, Iran

City
Tehran

Postal code

Person responsible for scientific inquiries

Contact

Name of organization / entity
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Dr. Sahraee Zahra

Position
Board Certified Pharmacotherapy Specialist

Other areas of specialty/work

Street address
Shahid Beheshti University of Medical Sciences, Arabi
Ave, Daneshjoo Blvd, Velenjak, Tehran, Iran

City
Tehran

Postal code

Phone
+98 21 8820 0118

Fax

Email
zahra.sahraee@yahoo.com

Web page address

Person responsible for updating data

Contact

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