Clinical Trial Protocol
Iranian Registry of Clinical Trials

31 Oct 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 threatment; 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

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Zahra Sahraei
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Faculty of pharmacy, Shahid beheshti university of medical sciences
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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

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Dr. Nima Naderi
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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
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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