Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Evaluation of the effectiveness of intrathecal versus intraventricular antimicrobial therapy for bacterial meningitis following craniotomy: a clinical trial

Protocol summary

Study aim
Comparing the effectiveness of intravenous and intraventricular antimicrobial therapy for bacterial meningitis following craniotomy

Design
A controlled, parallel-group, single-blind, randomized, simple random assignment clinical trial, phase 3, on 30 patients.

Settings and conduct
The present study will be conducted in the ICU of Golestan Hospital, Ahvaz. The study population is patients with meningitis caused by gram-negative bacteria after craniotomy and EVD infection simultaneously or during hospitalization according to CDC criteria. Blinding in the present study will be performed at the level of participant, data analyst, and outcome assessor.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Patients aged 16-80 years with meningitis caused by gram-negative bacteria after craniotomy and EVD insertion simultaneously or during hospitalization, patient consent. Exclusion criteria: History of shunt placement, previous brain or spinal surgery, recent antibiotic intake, sensitivity to study drugs, renal dysfunction, and death during the study.

Intervention groups
intravenous treatment including, 2 grams of meropenem (2 g/kg/day) every 8 hours if the culture result is gram-negative, and 1 gram of vancomycin (1 g/kg/day) every 12 hours if the culture result is gram-positive, along with intracranial treatment: 125 units of colistin daily (125 IU q24h) and 80 grams of vancomycin daily (80 g/kg/day) if the culture result is gram-positive. The control group: intravenous treatment including, 2 grams of meropenem (2 g/kg/day) every 8 hours if the culture result is gram-negative, and 1 gram of vancomycin (1 g/kg/day) every 12 hours if the culture result is gram-positive

Main outcome variables
14-day mortality, length of stay in ICU, positive blood culture, need for tracheostomy, duration of positive CSF culture and biochemistry smear results

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20260518069437N1**
Registration date: **2026-08-02, 1405/05/11**
Registration timing: **prospective**

Last update: **2026-08-02, 1405/05/11**
Update count: **0**

Registration date
2026-08-02, 1405/05/11

Registrant information
Name
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Recruitment status
recruiting
Funding source

Expected recruitment start date
2026-08-08, 1405/05/17
Expected recruitment end date
2027-03-01, 1405/12/10
Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effectiveness of intrathecal versus intraventricular antimicrobial therapy for bacterial meningitis following craniotomy: a clinical trial

Public title

Comparison of treatment methods for microbial infection in patients with meningitis.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients aged 16-80 years with meningitis caused by gram-negative bacteria after craniotomy Concurrent or in-hospital external ventricular drain (EVD) infection Patient consent to participate in the study

Exclusion criteria:

History of shunting Previous brain or spinal surgery Recent antibiotic use Sensitivity to study drugs Renal dysfunction Death during the study

Age

From **20 years** old

Gender

Both

Phase

3

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, simple randomization will be used to allocate patients to two parallel groups (intrathecal versus intraventricular therapy) with a 1:1 allocation ratio. The randomization unit is the individual patient. Random allocation will be performed using a computer-generated random number table to ensure that each participant has an equal probability of being assigned to either study arm. To implement this, sequentially numbered, opaque, sealed envelopes (SNOSE) containing the group assignments (odd numbers for the intrathecal group and even numbers for the intraventricular group) will be prepared. Upon enrollment and after obtaining informed consent, the coordinator will open the corresponding envelope in sequence. The allocation sequence will be concealed from both the principal investigators and the outcome assessors. Potential confounding factors, including the presence of an external ventricular drain (EVD), primary indication for craniotomy, age, gender, and underlying comorbidities, will be controlled during the data analysis stage using stratification or multivariate regression models.

Blinding (investigator's opinion)

Single blinded

Blinding description

Due to the nature of the intervention, blinding of participants and healthcare providers (physicians and nurses involved in delivering the intervention) is not feasible; therefore, they will be aware of group allocation. However, blinding will be implemented at the level of outcome assessment and data analysis. Outcome assessors responsible for data collection and outcome recording will be blinded to group allocation and will only identify participants using coded labels (A and B). In addition, the statistician performing data analysis will be blinded to treatment allocation, and all analyses will be conducted using anonymized and coded datasets without access to intervention-related information.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethical Committee of Ahvaz Jundishapur University of Medical Sciences

Street address

Second Floor, Research Vice-Chancellor Building, Ahvaz Jundishapur University, Golestan Highway, Iran

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ahvaz

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Postal code

61357-15794

Approval date

2026-06-27, 1405/04/06

Ethics committee reference number

IR.AJUMS.REC.1405.135

Health conditions studied

1

Description of health condition studied

Meningitis

ICD-10 code

A87.9

ICD-10 code description

Viral meningitis, unspecified

Primary outcomes

1

Description
Positive blood culture
Timepoint
In time of treatment initiation up to discharge time
Method of measurement
Culture of blood sample in the laboratory

2

Description
Need to tracheostomy
Timepoint
Every day following treatment initiation
Method of measurement
To perform or not to perform a tracheostomy

3

Description
Mortality
Timepoint
14 days following treatment initiation
Method of measurement
Alive or expired

4

Description
Duration of admission in ICU
Timepoint
The day of discharge from ICU
Method of measurement
Day count

5

Description
The time of blood culture results to be positive
Timepoint
In time of treatment initiation up to discharge time
Method of measurement
Day count

6

Description
CSF biochemistry smear
Timepoint
In time of treatment initiation up to discharge time
Method of measurement
Laboratory assessment

Secondary outcomes

1

Description
Neurological deterioration
Timepoint
Every day following treatment initiation
Method of measurement
Brain imaging

2

Description
Mortality
Timepoint
30 days following treatment initiation
Method of measurement
Alive or expired

Intervention groups

1

Description
Intervention group: Intravenous treatment: 2 g of meropenem every 8 hours if the culture result is gram-negative, and 1 g of vancomycin every 12 hours if the culture result is gram-positive. In addition to the intravenous treatment mentioned above, intracranial treatment is also given with 125 units of colistin daily if the culture result is gram-negative, and 80 g of vancomycin daily if the culture result is gram-positive. Empirical treatment, including ceftazidime and vancomycin twice daily or according to the results of the Gram stain, will be given. Definitive treatment is determined based on sensitivities, with a preference for narrow-spectrum beta-lactams. Treatment will continue until definitive improvement is confirmed based on laboratory culture results.
Category
Treatment - Drugs

2

Description
Control group: Intravenous treatment is 2 g of meropenem every 8 hours if the culture result is gram-negative, and 1 g of vancomycin every 12 hours if the culture result is gram-positive. Empirical treatment includes ceftazidime and vancomycin twice a day or according to the results of the Gram stain. Definitive treatment is determined based on sensitivities, with a preference for narrow-spectrum beta-lactams. Treatment is continued until definitive improvement based on laboratory culture results.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
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Full name of responsible person
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Sponsors / Funding sources

1

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Grant name

Grant code / Reference number

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

Title of funding source
Ahvaz University of Medical Sciences

Proportion provided by this source
70

Public or private sector
Public

Domestic or foreign origin
Domestic

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact

Name of organization / entity
Ahvaz University of Medical Sciences

Full name of responsible person
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Position
Assistant Professor

Latest degree
Specialist

Other areas of specialty/work
Neurosurgery

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
There is no more information.
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available
Title and more details about the data/document
The raw data file will not be made available to other researchers. The results of the data analysis will be published in the form of an article only after the study is completed.
When the data will become available and for how long
The raw data file will not be made available to other researchers.
To whom data/document is available
There is no more information.
Under which criteria data/document could be used
There is no more information.
From where data/document is obtainable
Dr. Armin Jahangiri babadi, armin57.jb@gmail.com
What processes are involved for a request to access data/document
It is available after correspondence with Dr. Armin Jahangiri Babadi. It is important to note that only the editor of the journal to which the article will be submitted will be allowed to request access to the data to prove the reliability and trustworthiness of the results. After going through these steps, access will be available approximately 1 week later.
Comments