Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Evaluation of the effect of local wound irrigation with vancomycin on reduction shunt infection in children with hydrocephalus

Protocol summary

Study aim
Determining the effect of local irrigation with vancomycin in reducing shunt infection in children with hydrocephalus

Design
This study is a randomized double-blind control trial on 143 patients with parallel groups, in 2 control and intervention groups.

Settings and conduct
Patients admitted to Mashhad Akbar children's hospital will be randomly divided into control and intervention groups. In the intervention group, after fixing the shunt and inserting the catheter and before closing the scalp and abdomen incision site, washing the surgical site with vancomycin (one vial of vancomycin combined with normal saline solution to the amount of 5 cc. 2.5 cc of the above solution will be used for irrigation of the head incision site and 2.5 cc for the abdominal incision site) and in the control group, irrigation will be done only with normal saline.

Participants/Inclusion and exclusion criteria
Inclusion criteria: children under 15 years old with a definitive diagnosis of hydrocephalus, candidates for ventriculoperitoneal shunt surgery. Exclusion criteria: previous history of meningitis or shunt infection, surgery in the CNS system from 3 months before to 6 months after shunt insertion, immune system dysfunction, repeated CSF drainage in the last 3 months (EVD , LP, Ventricular Tap), any abdominal surgery in the last 3 months, lack of available data in terms of study variables or exclusion criteria, any manipulation including shunt revision or tap in 6 months after shunt placement

Intervention groups
After catheter insertion and before closing the scalp and abdomen incision sites, irrigation of the surgical site will be done with vancomycin in the intervention group, and with normal saline in the control group.

Main outcome variables
The rate of shunt infection based on patients' visits to the hospital, hospitalizations and positive culture of cerebrospinal fluid

General information

Reason for update

Acronym
-

IRCT registration information
IRCT registration number: **IRCT20240814062757N1**
Registration date: **2024-12-03, 1403/09/13**
Registration timing: **prospective**

Last update: **2024-12-03, 1403/09/13**
Update count: **0**

Registration date
2024-12-03, 1403/09/13

Registrant information

Name
Marzieh Maleki

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 51 3844 2433

Email address
malekim991@mums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2024-12-21, 1403/10/01

Expected recruitment end date
2025-04-19, 1404/01/30

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of local wound irrigation with vancomycin on reduction shunt infection in children with hydrocephalus

Public title

Evaluation of the effect of local wound irrigation on reduction shunt infection

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Children under 15 years of age with definitive diagnosis of hydrocephalus who are candidates for ventriculoperitoneal shunt surgery.

Exclusion criteria:

Previous history of meningitis or shunt infection Any surgery in the CNS system in the last 3 months before shunt insertion or 6 months after shunt insertion Any dysfunction of the immune system, history of repeated CSF drainage in the last 3 months (ventricle tap, LP, EVD) History of any abdominal surgery in the last 3 months Lack of available data in terms of study variables or exclusion criteria, any manipulation including revision or shunt tap within 6 months after shunt insertion.

Age

From **1 day** old to **15 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **143**

Randomization (investigator's opinion)

Randomized

Randomization description

Blocking will be used for random allocation. Blocks with random sizes will be used. The obtained sequence is only available to the main therapist. Patients and analysts will be unaware of the allocation. Concealment will be done using a closed envelope, patients will receive the envelope on the day of surgery by the researcher and hand it over to the surgeon before surgery.

Blinding (investigator's opinion)

Double blinded

Blinding description

Concealment will be done using a closed envelope, patients will receive the envelope on the day of surgery by the researcher and hand it over to the surgeon before surgery. In this study, the main researcher knows the grouping of patients (control or intervention group) and delivers the type of grouping to the patients in the form of a closed envelope. Patients hand over the envelope to the professor before surgery. Also, the data analyst is unaware of the grouping of patients

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of School of Medicine, Mashhad University of Medical Sciences

Street address

Shahid Fakuri Blvd., Knowledge and Health Borough, Central Organization of Mashhad University of Medical Sciences

City

Mashhad

Province

Razavi Khorasan

Postal code

9177899191

Approval date

2024-07-23, 1403/05/02

Ethics committee reference number

IR.MUMS.MEDICAL.REC.1403.261

Health conditions studied

1

Description of health condition studied

Hydrocephalus

ICD-10 code

G91.9

ICD-10 code description

Hydrocephalus, unspecified

Primary outcomes

1

Description

Percentage of patients with shunt infection

Timepoint

Specialist visit in 3 months after shunt insertion

Method of measurement

Examination by a neurosurgeon

Secondary outcomes

empty

Intervention groups

1

Description
A vial of vancomycin mixed with normal saline solution is added to 5 cc and 2.5 cc of the above solution is washed in the head incision site and 2.5 cc in the abdominal incision site.
Category
Prevention

2

Description
Local irrigation of the incision site of the head and abdomen with normal saline
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Akbar Hospital
Full name of responsible person
Marzieh Maleki
Street address
Kaveh Blvd., TV Square
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9177897157
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+98 51 3871 3801
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malekim991@mums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Mohsen Tafaghodi
Street address
Faculty of Medicine, Mashhad University Of Medical Sciences, Azadi Square
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tafaghodim@mums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Mashhad University of Medical Sciences
Proportion provided by this source
100
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
Mashhad University of Medical Sciences
Full name of responsible person
Marzieh Maleki
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
Neurosurgery
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No. 206, Between 14 and 16 Hemmat Alley, Beheshti Blvd., Mashhad
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
Patient information such as age, sex, head circumference, cause of hydrocephalus, type of shunt used, location of shunt, length of operation, number of surgeons, number of personnel, history of previous shunt, use or non-use of vancomycin solution will be published in a file.
When the data will become available and for how long
Access after printing the results
To whom data/document is available
Researchers working in scientific and academic institutions
Under which criteria data/document could be used
Non-identifiable data of individuals will be made available for use in relevant research and to check the accuracy of study results.
From where data/document is obtainable
To receive data, contact the corresponding author via email.
What processes are involved for a request to access data/document
The requester must share the reason for the need for the data with the responsible author via email, and the information will be made available at the discretion of the responsible author.
Comments