Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Determining the effect of local use of injectable vancomycin in preventing exit site infection in children with peritoneal dialysis

Protocol summary

Study aim
Evaluating the Effectiveness of Topical Vancomycin for the Treatment of Catheter Exit Infection in Children with Peritoneal Dialysis

Design
Semi-Experimental Non-randomized clinical trial No blinding or placebo on 40 patients

Settings and conduct
This Study is Conducted in Dr. Sheikh Hospital in Mashhad. Patients are treated with topical Vancomycin for 3 to 5 days and followed up for 6 months.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Children from 2 months to 18 years old with Peritoneal Dialysis in Dr .Sheikh Hospital in Mashhad Exclusion criteria: Children with Vancomycin Allergy and parents with dissatisfaction to participate

Intervention groups
Peritoneal Dialysis Children with Catheter Exit site Infection treated with Topical Vancomycin, does not have a control group.

Main outcome variables
Abundance and percentage of recovery of infection based on improvement of clinical symptoms

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20240106060632N1**
Registration date: **2024-08-12, 1403/05/22**
Registration timing: **prospective**

Last update: **2024-08-12, 1403/05/22**
Update count: **0**

Registration date
2024-08-12, 1403/05/22

Registrant information

Name
Fatemeh Saberi

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 51 3878 4051

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f.saberi.73@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2024-08-21, 1403/05/31

Expected recruitment end date
2025-02-17, 1403/11/29

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Determining the effect of local use of injectable vancomycin in preventing exit site infection in children with peritoneal dialysis

Public title
Determining the effect of local use of injectable vancomycin in preventing exit site infection in children with peritoneal dialysis

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Receiving Peritoneal Dialysis 2 Months to 18 years old Not having a history of Vancomycin Allergy Absence of Underlying Dermatologic Diseases based on initial

clinical evaluation Informed Consent Not Receiving Systemic Antibiotics in last month

Exclusion criteria:

Sensitivity to Vancomycin Younger than 2 Month old

Age

From **2 months** old to **18 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Other

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Mashhad University of Medical Science

Street address

Ethicscommittee , Mashhad University of Medical Sciences, Vakil Abad Street

City

Mashhad

Province

Razavi Khorasan

Postal code

9177748153

Approval date

2023-09-09, 1402/06/18

Ethics committee reference number

IR.MUMS.REC.1402.162

Health conditions studied

1

Description of health condition studied

Exit site infection of peritoneal dialysis

ICD-10 code

K65.0

ICD-10 code description

Generalized (acute) peritonitis

Primary outcomes

1

Description

Peritoneal Dialysis exit site infection

Timepoint

1 Week , 3 Month , 6 Month

Method of measurement

Physical exam

Secondary outcomes

1

Description

Infectious Peritonitis

Timepoint

3 Month and 6 Month

Method of measurement

Clinical signs and peritoneal fluid culture

Intervention groups

1

Description

Intervention group: Intervention group: Patients in the topical vancomycin intervention group will receive 1 cc of vancomycin with a concentration of 100 mg/ml or 200 mg/ml based on Scourefont. Control group: none

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Clinic of Dr. Sheikh Mashhad

Full name of responsible person

Fatemeh Saberi

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Dr. Sheikh Hospital, Dr. Sheikh Street 3, Motahari Street , Mashhad

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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mashhad University of Medical Sciences
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Dr. Mohsen Tafaghodi
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presidentoffice@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
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to

make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be 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

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available