Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Comparison of complications of conventional peritoneal catheters with nephrostomy catheter in children with acute kidney failure undergoing Acute peritoneal dialysis

Protocol summary

Study aim

Determination and comparison of complications (peritonitis, temporary leakage of dialysis fluid, hernia, etc.) of rigid peritoneal catheters with nephrostomy tube in infants and children with acute kidney failure undergoing peritoneal dialysis in Dr. Sheikh and Ghaem Mashhad Hospital

Design

This research is a non-blind randomized clinical trial study that will be performed on 50 patients hospitalized in the ICU departments of Dr. Sheikh and Ghaem Mashhad Hospital during 2023, 2024 and 2025. The research includes neonates, infants and children with acute kidney failure who undergo acute peritoneal dialysis due to the indications of emergency dialysis.

Settings and conduct

Peritoneal dialysis center in the special care department for infants and children in Ghaem, Sheikh, Imam Reza and Akbar Hospitals The number of 50 participating patients who have the study entry criteria will be placed in two groups of rigid peritoneal catheters and nephrostomy tube group by simple randomization method. Due to the nature of the study, blinding will not be performed.

Participants/Inclusion and exclusion criteria

Children and infants with acute kidney failure undergoing peritoneal dialysis between the ages of 0-12 years

Intervention groups

The intervention group includes infants and children who undergo acute peritoneal dialysis with a nephrostomy catheter, and the control group includes infants and children who undergo acute peritoneal dialysis with a rigid acute catheter.

Main outcome variables

The number of peritonitis - dialysis catheter performance - acute catheter leakage rate - patient recovery - need for chronic dialysis - death

General information

Reason for update

the sample size was entered incorrectly

Acronym

IRCT registration information

IRCT registration number: **IRCT20230809059093N1**
Registration date: **2023-08-19, 1402/05/28**
Registration timing: **registered_while_recruiting**

Last update: **2026-08-18, 1405/05/27**
Update count: **2**

Registration date

2023-08-19, 1402/05/28

Registrant information

Name

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Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-05-22, 1402/03/01

Expected recruitment end date

2025-03-20, 1403/12/30

Actual recruitment start date

2023-05-22, 1402/03/01

Actual recruitment end date

2025-03-20, 1403/12/30

Trial completion date

2025-09-09, 1404/06/18

Scientific title
Comparison of complications of conventional peritoneal catheters with nephrostomy catheter in children with acute kidney failure undergoing Acute peritoneal dialysis

Public title
Comparison of complications of two types of catheter in children undergoing Acute peritoneal dialysis

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Children and infants with acute kidney failure undergoing peritoneal dialysis Children and infants between the ages of 0-12 years

Exclusion criteria:

Age
From **1 day** old to **12 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **50**
Actual sample size reached: **50**

Randomization (investigator's opinion)
Randomized

Randomization description
Simple randomization

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
Research Ethics Committee of the Faculty of Medicine, Mashhad University of Medical Sciences

Street address
Faculty of Medicine, Mashhad University of Medical Sciences, Kalantari Highway

City
Mashhad

Province
Razavi Khorasan

Postal code
9177948564

Approval date
2023-06-27, 1402/04/06

Ethics committee reference number
IR.MUMS.MEDICAL.REC.1402.188

Health conditions studied

1

Description of health condition studied
Peritoneal Dialysis

ICD-10 code
N18.5

ICD-10 code description
Chronic kidney disease, stage 5

Primary outcomes

1

Description
The primary measurable outcome is the performance of nephrostomy catheter versus acute peritoneal catheter according to age.

Timepoint
Patients are examined within 1 to 20 days in terms of complications and outcomes, including spontaneous withdrawal of the catheter - catheter infection - leakage of the catheter site - lack of function - recovery of the patient - need for chronic dialysis - death despite good catheter performance. In the intervention group, a nephrostomy catheter is used for acute dialysis.

Method of measurement
Observation of catheter function

Secondary outcomes

1

Description
Secondary measurable outcomes are peritonitis rate and fluid leakage rate in nephrostomy catheter compared to acute peritoneal catheter.

Timepoint
Patients are examined within 1 to 20 days in terms of complications and outcomes, including spontaneous withdrawal of the catheter - catheter infection - leakage of the catheter site - lack of function - recovery of the patient - need for chronic dialysis - death despite good catheter performance. In the intervention group, a nephrostomy catheter is used for acute dialysis. For all cases, a culture and smear from the returned peritoneal fluid is sent from the first day, and all necessary information is recorded in terms of leakage from the catheter and malfunction or peritoneal peritonitis (the presence of white blood cells more than 100 and a positive peritoneal culture). In the case of infection, the catheter will be replaced. After collecting the data, statistical analysis will be done.

Method of measurement

Culture and smear of peritoneal return fluid

Intervention groups

1

Description
Control group: In this group, infants and children (25 person) are subjected to intraperitoneal catheterization according to the type of underlying disease and the indications that require acute dialysis. The conventional method is to use a rigid catheter, which has only one size from newborn to adult, and it should be shortened for infants. This catheter can be placed in the patient's body by open surgery through the skin or laparoscopically.
Category
Treatment - Devices

2

Description
Intervention group: In this group, a nephrostomy catheter is used for acute dialysis. Performing the intervention is the same as catheterization in the control group in terms of possible risks. (25 person)
Category
Treatment - Devices

Recruitment centers

1

Recruitment center
Name of recruitment center
Dr. Sheikh Hospital
Full name of responsible person
Yasamin Nakhaee Moghaddam
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Dr. Sheikh Children's Hospital, Dr. Sheikh Street, Tohid Sq.
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Sponsors / Funding sources

1

Sponsor
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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
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
Sara Saadat
Position
Associate professor
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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

Trial results

Please tick if results have been published
Yes
Summary result posting date
2026-08-18, 1405/05/27
Table of baseline comparison
Participant flow diagram
Table of variable outcomes' results
Table of adverse events
First publication date
2026-05-30, 1405/03/09
Abstract of published paper
Background: Acute kidney injury (AKI) is a serious problem among hospitalized children and is associated with adverse outcomes. Peritoneal dialysis is the preferred modality for treating AKI in children. Nephrostomy catheters may serve as an alternative to rigid catheters, given the latter’s suboptimal design and associated complications. Objectives: This study aimed to compare catheter-related complications between nephrostomy and rigid catheters in children with AKI who required acute peritoneal dialysis. Methods: In this randomized clinical trial, children aged 0 - 12 years with AKI requiring urgent peritoneal dialysis were randomly assigned to receive either a rigid catheter (control group) or a nephrostomy catheter (intervention group). Demographic and clinical data were collected, and outcomes included catheter-related complications. Results: A total of 50 children were enrolled. Catheter leakage occurred in 28% of patients in the rigid catheter group and 20% in the nephrostomy group (odds ratio [OR] = 0.64; 95% confidence interval [CI], 0.17 - 2.38; P = 0.50). The mean duration of catheter use differed significantly between the groups, with a mean difference of 2.24 days (95% CI, 0.18 - 4.29; P = 0.02). No significant differences were observed between the 2 groups in

peritonitis, exit-site infection, the need for chronic dialysis, or mortality (all $P > 0.05$). Conclusions: Both catheter types are feasible for acute peritoneal dialysis in children with AKI. However, because nephrostomy catheters had a significantly longer catheter survival duration, their use may offer a relative advantage in specific conditions. Multicenter studies with larger sample sizes are recommended to confirm these findings. Keywords: Nephrostomy Catheter, Acute Kidney Injury, Pediatric, Peritoneal Dialysis, Rigid Catheter