

Clinical Trial Protocol

Iranian Registry of Clinical Trials

24 Jul 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: **2025-04-20, 1404/01/31**

Update count: **1**

Registration date

2023-08-19, 1402/05/28

Registrant information

Name

Yasamin Nakhaee Moghaddam

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 51 3845 4753

Email address

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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

Street address

Dr. Sheikh Children's Hospital, Dr. Sheikh Street, Tohid Sq.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Dr. Sara Saadat

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Sheikh.hos@mums.ac.ir

Web page address

<https://sheikh.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

Sara Saadat

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

Pediatric Nephrology

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Person responsible for scientific inquiries

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Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Sara Saadat

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

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Person responsible for updating data

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Full name of responsible person

Yasamin Nakhaee Moghaddam

Position

Medical Student

Latest degree

Medical doctor

Other areas of specialty/work

General Practitioner

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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