

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

11 Jul 2026

### Randomized clinical trial to compare the outcomes of percutaneous technique and open surgical peritoneal dialysis catheter placement in children with chronic renal failure

#### Protocol summary

##### Summary

This research compared the outcomes of percutaneous technique and open surgical peritoneal dialysis catheter placement in children. This randomized controlled trial will perform in the department of pediatric nephrology and vascular surgery of Isfahan Alzahra university hospital. Informed consent will obtain from the parents of children taking part in our study. A total of 35 pediatric uremic patients will enroll and randomize into two study groups by random allocation software. Follow up data of this study include duration of operation (minute) ,duration of hospitalization (days) and onset time of peritoneal dialysis. Complications consider as mechanical and infectious.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2013091514670N1**

Registration date: **2013-09-23, 1392/07/01**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2013-09-23, 1392/07/01

##### Registrant information

##### Name

Sayed Mahdi Marashi

##### Name of organization / entity

Legal Medicine Organization

##### Country

Iran (Islamic Republic of)

##### Phone

+98 917 916 7438

##### Email address

marashi\_m@razi.tums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Isfahan University of Medical Sciences

##### Expected recruitment start date

2010-09-23, 1389/07/01

##### Expected recruitment end date

2011-09-10, 1390/06/19

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Randomized clinical trial to compare the outcomes of percutaneous technique and open surgical peritoneal dialysis catheter placement in children with chronic renal failure

##### Public title

Peritoneal dialysis catheter insertion

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion criteria: patients who will be receiving peritoneal dialysis and have family support. Exclusion criteria: history of prior major abdominal surgery; ventral or inguinal hernia AND BMI  $\geq 35$  kg/m<sup>2</sup>.

##### Age

To **15 years** old

##### Gender

Both

##### Phase

N/A

### Groups that have been masked

No information

### Sample size

Target sample size: 35

### Randomization (investigator's opinion)

Randomized

### Randomization description

### 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

Isfahan University of Medical Sciences

##### Street address

Hezar Jarib St. Isfahan University of Medical Sciences,  
Deputy of Research

##### City

Isfahan

##### Postal code

81746-73461

##### Approval date

2009-07-27, 1388/05/05

##### Ethics committee reference number

288132

## Health conditions studied

### 1

#### Description of health condition studied

Peritoneal dialysis catheter insertion

#### ICD-10 code

N 18.5

#### ICD-10 code description

End-stage kidney disease

## Primary outcomes

### 1

#### Description

catheter outflow

#### Timepoint

weekly for 2 months

#### Method of measurement

sufficient catheter outflow

## Secondary outcomes

### 1

#### Description

Hemoperitoneum

#### Timepoint

daily for 3 days

#### Method of measurement

reddish change in color of fluid

### 2

#### Description

exit site infection

#### Timepoint

days1,3,7,30,60

#### Method of measurement

examination

### 3

#### Description

peritonitis

#### Timepoint

daily for first 3days

#### Method of measurement

examination

## Intervention groups

### 1

#### Description

Intervention group: percutaneous PDC; percutaneous method with secure insertion of the catheter reduced the rate of some complications, although they were not statistically significant but this technique reduces the time of hospitalization and operation without need to general anesthesia. The onset of dialysis was earlier significantly.

#### Category

Treatment - Surgery

### 2

#### Description

Control group: conventional open surgical method

#### Category

Treatment - Surgery

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Isfahan alzahra hospital

##### Full name of responsible person

Hojatollah raji-general surgeon

##### Street address

Soffe blv. alzahra hospital

**City**  
Isfahan

## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**  
Isfahan University of Medical Sciences  
**Full name of responsible person**  
Dr Hafez Ghaheri  
**Street address**  
Alzahra hospital  
**City**  
Isfahan

### Grant name

### Grant code / Reference number

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

Yes

### Title of funding source

Isfahan University of Medical Sciences

### Proportion provided by this source

100

### Public or private sector

*empty*

### Domestic or foreign origin

*empty*

### Category of foreign source of funding

*empty*

### Country of origin

### Type of organization providing the funding

*empty*

## Person responsible for general inquiries

### Contact

**Name of organization / entity**  
Legal medicine research center  
**Full name of responsible person**  
Sayed Mahdi Marashi  
**Position**  
Forensic medicine specialist  
**Other areas of specialty/work**  
**Street address**  
south side of City Park, Behesht Street,  
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Tehran  
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1114795113  
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drmr44@yahoo.com  
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## Person responsible for scientific

## inquiries

### Contact

**Name of organization / entity**  
Department of general surgery  
**Full name of responsible person**  
Hojatollah Raji  
**Position**  
General surgeon  
**Other areas of specialty/work**  
**Street address**  
Alzahra hospital  
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**Web page address**

## Person responsible for updating data

### Contact

**Name of organization / entity**  
Legal medicine organization  
**Full name of responsible person**  
Sayed Mahdi Marashi  
**Position**  
Forensic medicine specialist  
**Other areas of specialty/work**  
**Street address**  
South side of City Park, Behesht Street,  
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drmr44@yahoo.com  
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## Sharing plan

### Deidentified Individual Participant Data Set (IPD)

*empty*

### Study Protocol

*empty*

### Statistical Analysis Plan

*empty*

### Informed Consent Form

*empty*

### Clinical Study Report

*empty*

### Analytic Code

*empty*

