Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

New Laparoscopic technique (preperitoneal tunneling) vs open surgical placement of peritoneal dialysis catheter

Protocol summary

Summary

Purpose: Comparing the follow up results of the patients operated by prepritoneal tunneling tecknique with the patients operated by open surgery. Study method: non random interventional. Study Population: The ESRD (end stage renal disease) patients comming to Emam Reza and Ghaem's nephrology clinics, Mashhad, Iran. Inclusion criteria: the patients should have the capacity to know how to take care of peritoneal dialysis Catheter and follow the given instructions. Exclusion criteria: The patients who do not refer to the hospital for the follow up check ups or they are not accessible in anyway. Sample size: 200 patients. Intervention: using laparoscopic preperitoneal tunneling tecknique or open surgery for laparoscopic CAPD catheter placement. Outcome: peritonitis, inflow and outflow of dialysis fluid, catheter migration, cath. block, Omental wrapping, tunnel infection, leak, port-site hernia.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138810231820N2**
Registration date: **2011-04-18, 1390/01/29**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2011-04-18, 1390/01/29

Registrant information

Name
Mohammad-Hadi Saeed Modaghegh
Name of organization / entity
Mashhad University of Medical Sciences
Country
Iran (Islamic Republic of)
Phone
+98 51 1802 2505
Email address
modaghegh@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Mashhad university of medical sciences

Expected recruitment start date

2001-03-21, 1380/01/01

Expected recruitment end date

2011-03-20, 1389/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

New Laparoscopic technique (preperitoneal tunneling) vs open surgical placement of peritoneal dialysis catheter

Public title

Preperitoneal tunneling: A novel technique in peritoneal dialysis catheter insertion

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: The patients should have the capacity to know how to take care of peritoneal dialysis Catheter and follow the given instructions. Exclusion criteria:The patients who do not refer to the hospital for the follow up check ups or they are not accessible in anyway.

Age

No age limit

Gender

Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **200**
Randomization (investigator's opinion)
Not randomized
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
Mashhad University of Medical Sciences
Street address
Ghoreyshi building, Daneshgah av.
City
Mashhad
Postal code
Approval date
2008-06-13, 1387/03/24
Ethics committee reference number
86181

Health conditions studied

1

Description of health condition studied
peritoneal dialysis catheter insertion
ICD-10 code
Z49
ICD-10 code description
Care involving dialysis

Primary outcomes

1

Description
Peritonitis
Timepoint
monthly
Method of measurement
inspection and examination

2

Description
Fluid flow
Timepoint
immediately after surgery then monthly
Method of measurement
examinatin

3

Description
Cath. migration
Timepoint
monthly
Method of measurement
KUB

4

Description
Omental wrapping
Timepoint
monthly
Method of measurement
laparoscopy

5

Description
Cath. block
Timepoint
monthly
Method of measurement
based on cath function

6

Description
Tunnel infection
Timepoint
monthly
Method of measurement
inspection and examination

7

Description
Leak
Timepoint
monthly
Method of measurement
inspection and examination

8

Description
Port site hernia
Timepoint
monthly
Method of measurement
Inspection and examination

Secondary outcomes

1

Description
Dialysis start time
Timepoint
weekly
Method of measurement
Observation

2

Description
Anesthesia duration
Timepoint
there is no Secondary outcome time point
Method of measurement
operation duration

Intervention groups

1

Description
Laparoscopic prepritoneal CAPD cath. placement
Category
Treatment - Surgery

2

Description
Control:open surgical technique for placement of CAPD cath.
Category
Treatment - Surgery

Recruitment centers

1

Recruitment center
Name of recruitment center
Endovascular research center, Emam Reza Hospital
Full name of responsible person
Rajabnejad Yaser
Street address
Emamreza hospital, Ebnesina av.
City
Mashhad

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Mr Bozorgnia
Street address
Emam Reza Hospital
City
Mashhad
Grant name
برنامه10506/فصل2
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
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
Mashhad Univesity of Medical Sciences
Full name of responsible person
Rajabnejad Yaser
Position
General practitioner
Other areas of specialty/work
Street address
Endovascular Research Center, Emam Reza Hospital
City
Mashhad
Postal code
Phone
+98 936 672 3271
Fax
Email
rajabnejady861@mums.ac.ir
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Endovascular Research Center, Mashhad University of Medical Sciences
Full name of responsible person
Dr. Hady Modaghegh
Position
Vascular Surgeon
Other areas of specialty/work
Street address
Emamreza Hospital
City
Mashhad
Postal code
Phone

+98 51 1852 5311

Fax

Email

modaghegh@mums.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Full name of responsible person

Rajabnejad Yaser

Position

General practitioner

Other areas of specialty/work

Street address

City

Postal code

9137913316

Phone

+98 51 1852 5311

Fax

+98 51 1852 5311

Email

raj.yaser@gmail.com

Web page address

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

Data Dictionary

empty