

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Jul 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 preperitoneal tunneling technique with the patients operated by open surgery. Study method: non random interventional. Study Population: The ESRD (end stage renal disease) patients coming 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 technique 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

examination

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 preperitoneal 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

برنامه 10506/فصل 2

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

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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

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Vascular Surgeon

Other areas of specialty/work

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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

Data Dictionary

empty