

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Jul 2026

Complications of open surgery versus laparoscopic technique in peritoneal dialysis catheter insertion

Protocol summary

Study aim

This study, aimed to assess the outcomes of open surgery versus laparoscopic technique, and compare their complications in those with survival of over and less than a year in patients who need PD for the first time.

Design

Clinical trial study with randomized parallel groups

Settings and conduct

It was conducted on 121 cases admitted for peritoneal dialysis at Alzahra university hospital affiliated to Isfahan University of Medical Sciences, Isfahan, Iran, during the years 2016-17

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients' requirement of peritoneal dialysis for the first time and Patients' willingness of participation in the study
Exclusion criteria: Patients who did not have tolerance of spinal or general anesthesia

Intervention groups

Open surgery and laparoscopy

Main outcome variables

Short-term and long-term surgery outcomes and complications

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190525043691N1**

Registration date: **2019-06-15, 1398/03/25**

Registration timing: **retrospective**

Last update: **2019-06-15, 1398/03/25**

Update count: **0**

Registration date

2019-06-15, 1398/03/25

Registrant information

Name

Alireza Amiran

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3435 8366

Email address

amiran_al@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-05-05, 1396/02/15

Expected recruitment end date

2018-09-06, 1397/06/15

Actual recruitment start date

2017-05-05, 1396/02/15

Actual recruitment end date

2018-11-25, 1397/09/04

Trial completion date

2018-11-25, 1397/09/04

Scientific title

Complications of open surgery versus laparoscopic technique in peritoneal dialysis catheter insertion

Public title

Complications of open surgery versus laparoscopic technique in peritoneal dialysis catheter insertion

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Patients' requirement of peritoneal dialysis for the first time
Patients' willingness of participation in the study

Exclusion criteria:

Patients who did not have tolerance of spinal or general anesthesia

Age

No age limit
Gender
Both
Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **120**
Actual sample size reached: **121**
Randomization (investigator's opinion)
Randomized
Randomization description
Patients were divided into two groups randomly in simple method using Random Allocation software (version 1.0). In this method, all patients were provided a number by the software, and those with even number were supposed as members of open surgery, and those with odd numbers were members of the other group.
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

The ethical committee of Isfahan School of Medicine

Street address

School of Medicine, Isfahan University of Medical Sciences, Hezar Jerib Ave.

City

Isfahan

Province

Isfahan

Postal code

8174673461

Approval date

2017-05-03, 1396/02/13

Ethics committee reference number

936183

Health conditions studied

1

Description of health condition studied

The outcomes and complication of of open surgery versus laparoscopic technique in catheter insertion

ICD-10 code

T85.6

ICD-10 code description

Mechanical complication of other specified internal and external prosthetic devices, implants and grafts

Primary outcomes

1

Description

Surgery outcomes and complications

Timepoint

12 months after the surgery

Method of measurement

observation and asking from the patient

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Open surgery

Category

Treatment - Surgery

2

Description

Intervention group: Laparoscopy

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center**Name of recruitment center**

Alzahra hospital

Full name of responsible person

Alireza Amiran

Street address

Alzahra Hospital, Sofeh Blv.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Shaghayegh Haghjoo Javanmard

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Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

No

Title of funding source

Alireza Amiran

Proportion provided by this source

100

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

Persons

Person responsible for general inquiries

Contact**Name of organization / entity**

Esfahan University of Medical Sciences

Full name of responsible person

Alireza Amiran

Position

Resident

Latest degree

Specialist

Other areas of specialty/work

General Surgery

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Person responsible for scientific inquiries

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Associate professor

Latest degree

Subspecialist

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Latest degree

Specialist

Other areas of specialty/work

General Surgery

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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

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

As an article, all the important data will be published.

When the data will become available and for how long

After completing data analysis, and for ever

To whom data/document is available

All the researchers without any limitation

Under which criteria data/document could be used

for multicentric research, and meta-analysis studies, it can be statistically analyzed again.

From where data/document is obtainable

They can send their requests to Alireza Amiran, via his email address (amiran_al@yahoo.com) or mailing address (Department of Surgery, Alzahra Hospital, Sofeh Blv., Isfahan, Iran).

What processes are involved for a request to access data/document

if it be proven to researchers that a person or institution really needs the data for a research, it will be set.

Comments