

Influence of the catheter exit site position on the risk of mechanical and infectious complications and technique survival in peritoneal dialysis patients.

Submission date 02/03/2015	Recruitment status No longer recruiting	☐ Prospectively registered
Registration date 10/03/2015	Overall study status Completed	☐ Protocol
Last Edited 09/03/2015	Condition category Urological and Genital Diseases	☐ Statistical analysis plan
		☐ Results
		☐ Individual participant data
		☐ Record updated in last year

Plain English summary of protocol

Background and study aims

Dialysis is a form of treatment that has been developed to take over the work of the kidney during end-stage kidney failure. It filters the blood, removing harmful waste, excess salt and excess water. There are two types of dialysis: haemodialysis and peritoneal dialysis (PD). Unlike haemodialysis, where the blood is filtered by an artificial membrane outside the body, peritoneal dialysis involves filtering the blood through the peritoneum, a thin membrane lining the outside of the abdominal organs. It works via the running of a dialysis fluid in and out of the peritoneal cavity, through a tube called a Tenckhoff Catheter. In order for the treatment to be successful, it is essential to obtain a continuous and secure access to the peritoneal cavity. Despite improvements in recent years, translocations and infections are still common and are a major cause for morbidity. More than 20% of PD patients need catheter removal and are permanently transferred to haemodialysis. One factor that could affect the incidence of such complications is the position of the catheter exit site. There is little evidence in the literature that suggest the best location of the exit site in relation to the risk of complications. This study will investigate whether the position of the catheter exit site influences the number of translocations and infections associated with peritoneal dialysis.

Who can participate?

Patients with chronic renal failure, age 18 and over, undergoing PD catheter implantation.

What does the study involve?

Participants are randomly allocated into one of two groups. Those in group 1 have their catheter implanted with the exit side down. Those in group 2 have their catheter implanted with the exit site up. The patients are then followed for one year and the following outcomes reported: translocations, peritonitis, infections of exit site and permanent transfer to haemodialysis.

What are the possible benefits and risks of participating?

Not provided at time of registration

Where is the study run from?

Nephrology Service of the Hospital das Clinicas de Botucatu – UNESP (Brazil)

When is the study starting and how long is it expected to run for?

July 2013 to July 2017

Who is funding the study?

Investigator initiated and funded

Who is the main contact?

Dr Vanessa Banin

Contact information

Type(s)

Scientific

Contact name

Dr Vanessa Banin

Contact details

Distrito de Rubião Junior

Botucatu

Brazil

18609363

Additional identifiers

Protocol serial number

N/A

Study information

Scientific Title

Influence of the catheter exit site position on the risk of mechanical and infectious complications and technique survival in peritoneal dialysis patients: a randomised controlled trial

Study objectives

Catheter exit site position influences translocations rate and infectious complications associated with peritoneal dialysis, and also can affect the survival of the method.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Local Ethics Committee in research, 06/04/2013

Study design

Randomised controlled trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Patients with chronic renal failure over 18 years of age and peritoneal dialysis incidents.

Interventions

Implant of peritoneal dialysis catheter being executed in two different ways:

1. Catheter implantation with exit site down
2. Catheter implantation with exit site up

Intervention Type

Procedure/Surgery

Primary outcome(s)

Permanent transfer to haemodialysis

Key secondary outcome(s))

1. Translocations
2. Peritonitis
3. Infections of exit site

Completion date

01/07/2017

Eligibility**Key inclusion criteria**

Patients with chronic renal failure over 18 years of age and peritoneal dialysis incidents, followed by the Nephrology Service of the Hospital das Clinicas de Botucatu - UNESP - Brazil.

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Key exclusion criteria

1. Loss to follow-up
2. Recovery of renal function
3. Renal transplantation
4. Death
5. Change elective of method of dialysis

Date of first enrolment

01/07/2013

Date of final enrolment

01/12/2016

Locations

Countries of recruitment

Brazil

Study participating centre

Nephrology Service of the Hospital das Clinicas de Botucatu - UNESP

District of Rubião Junior

Botucatu

Brazil

18609363

Sponsor information

Organisation

University UNESP Botucatu

ROR

<https://ror.org/00987cb86>

Funder(s)

Funder type

Not defined

Funder Name

investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Other