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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

Registration date
10/03/2015

Overall study status
Completed

Last Edited
09/03/2015

Condition category
Urological and Genital Diseases

[_] Prospectively registered
[_] Protocol
[_] 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
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18609363

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

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 measure
Permanent transfer to haemodialysis

Secondary outcome measures
1. Translocations
2. Peritonitis
3. Infections of exit site

Overall study start date
01/07/2013

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
To provide a statistical power of 80 %, with Beta error of 20% and identify a minimum difference of 40% between the two groups regarding the frequency of translocations, are required 30 patients in each group, a total of 60 patients.

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

Sponsor details
Distict of Rubião Junior
Botucatu
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Sponsor type
University/education

Website
www.fmb.unesp.br

ROR
https://ror.org/00987cb86

Funder(s)

Funder type
Not defined

Funder Name
investigator initiated and funded

Results and Publications

Publication and dissemination plan

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Other