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Radiological versus surgical implantation of catheter for peritoneal dialysis in the management of life-threatening end-stage kidney disease

Submission date
31/05/2011

Recruitment status
No longer recruiting

Registration date
10/06/2011

Overall study status
Completed

Last Edited
20/10/2016

Condition category
Urological and Genital Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Kidney failure, also called end-stage kidney disease (ESKD), is the last stage of chronic kidney disease. When the kidneys fail, it means they have stopped working well enough for the patient to survive without dialysis or a kidney transplant. Not all people are able to undergo a kidney transplant, and dialysis remains an important treatment for most people with ESKD. Dialysis patients have many health problems, often require the assistance of health professionals (mainly doctors and nurses), are frequently admitted to hospital and require several operations. If the number of operations, complications and discomfort from multiple health care visits can be reduced, this will help to reduce the emotional trauma to people with ESKD. There are two types of dialysis: peritoneal dialysis (PD) and haemodialysis (HD). Both types of dialysis require access to the body's blood to treat kidney failure. PD involves indirect access to the blood via the abdominal cavity (called the peritoneum), and requires a plastic tube (catheter) to be inserted through the abdominal wall into the peritoneum to allow a special fluid (dialysis fluid) to be drained in and out several times per day to "wash the blood" – taking over the job healthy kidneys do. The aim of this study is to test the success of a newer method of catheter insertion (radiological) to the standard method of catheter insertion (surgical). Before the study was done, it was thought that the radiological procedure (newer method) of insertion of the catheter would be a quicker and more cost-effective procedure, less stressful and less painful for participants when compared with the surgical method.

Who can participate?
Adult patients requiring PD for end-stage kidney disease

What does the study involve?
Participants are randomly allocated to undergo either the standard surgical method of catheter insertion (under general anaesthetic [asleep]) or the newer radiological method of catheter insertion (under local anaesthetic [awake]). All participants are then followed up for at least 12 months to observe the immediate success of the procedure of inserting the catheter, to ensure

that it worked, and to look for and compare the complications from the two different insertion procedures. Common problems include failure of the catheter to work due to blockage or movement within the abdomen, infection of the tube entry point on the skin, infection within the abdomen, hernia, and fluid leaking in to the wall of the abdomen. Complications are recorded by the study nurse telephoning the patient at monitoring points in the follow-up year after the catheter insertion and up to four community or hospital visits in this follow-up time.

What are the possible benefits and risks of participating?
The study participation risks fell into two categories: those risks potentially associated with the newer method; and those associated with ESKD and PD treatment in general. Most of the risks in this study can potentially occur in all people on PD whether they are study participants or not. These risks included: inability to insert the catheter for whatever reason; allergic reactions to the antibiotics required to prevent infection at the time of catheter insertion; bleeding from the wound or around the tube (catheter); infection around the catheter entering the skin (exit site infection); infection within the abdominal cavity (peritonitis); leakage of fluid from within the abdominal cavity into the chest, groin or abdominal wall; hernia; pain following the procedure. The radiological method involves a small amount of radiation exposure (several seconds of screening in X-ray room).

Where is the study run from?
Counties Manukau District Health Board (CMDHB) (New Zealand)

When is the study starting and how long is it expected to run for?
April 1999 to August 2004

Who is funding the study?
Counties Manukau District Health Board (CMDHB) (New Zealand)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Radiological versus surgical implantation of catheter for peritoneal dialysis: a randomised non-inferiority trial

Study objectives
The main objective of our study was to test the hypothesis that patients receiving peritonial dialysis (PD) catheters by radiological insertion technique (new intervention) had clinically equivalent outcomes to those by laparoscopic insertion (our standard) technique.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Auckland Ethics Committee, February 1999, ref: 98/234 (committee 10)

Study design
Single-centre interventional randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details to request a patient information sheet

Health condition(s) or problem(s) studied
End-stage kidney disease (ESKD)

Interventions

Participants were allocated by simple randomisation to receive the Baxter curl&reg catheter (Baxter Healthcare, McGaw Park, IL, USA) by either radiological or laparoscopic insertion technique. The randomisation procedure and treatment allocation was done by research staff not involved with the care of the participants, and performed before the initiation of dialysis. Randomisation allocations were stored in sequentially numbered opaque, sealed envelopes and were concealed and unavailable to investigators, study research staff and data entry staff at all points during the study. Because of the nature of the interventions, blinding of patients, providers, and data collectors was not possible.

After dialysis catheter insertion, all patients underwent continuous ambulatory PD using a Y-set system (Baxter Freeline solo®). All the participants were followed for one year following catheter insertion.

Intervention Type
Procedure/Surgery

Primary outcome measure
1. The occurrence of dialysis catheter complications by day 365, a composite endpoint that included complications secondary to mechanical causes (insertion failure, inflow/outflow failure, herniae, dialysate leak including those through the exit site, the diaphragm, a patent processus vaginalis, or an abdominal hernia), or infectious causes (PD-related peritonitis, exit site infection, catheter tunnel infection).
1.1. The mechanical complications were defined according to standard clinical criteria, except herniae and dialysate leaks which were defined by confirmatory appearances on computed tomographic (CT) peritoneography.
1.2. The infectious complications were defined according to International Society of Peritoneal Dialysis (1996) criteria

Secondary outcome measures
The occurrence of catheter removal and death from any cause

Overall study start date
01/04/1999

Completion date
30/08/2004

Eligibility

Key inclusion criteria
1. Participants were recruited from the outpatient clinic within the Counties Manukau District Health Board, South Auckland, New Zealand. Participants with severe or end-stage kidney disease were approached to participate in the study if they were offered and accepted PD as their renal replacement modality.
2. Individuals were eligible if they were over 18 years and suitable for both laparoscopic and radiological PD catheter insertion

Participant type(s)
Patient

Age group

Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
113

Key exclusion criteria
1. Severe obesity body mass index (BMI) > 35
2. Previous abdominal surgery or a history consistent with adhesions, severe medical co-morbidity precluding general anaesthesia, bleeding diatheses or anticoagulation
3. Human immunodeficiency virus (HIV) infection
4. Ongoing corticosteroid or immunosuppressant use
5. Severe psychiatric disease
6. Definite plans for live-donor kidney transplantation

Date of first enrolment
01/04/1999

Date of final enrolment
30/08/2004

Locations

Countries of recruitment
New Zealand

Study participating centre
Counties Manukau District Health Board
Auckland
New Zealand
1640

Sponsor information

Organisation
Counties Manukau District Health Board (CMDHB) (New Zealand)

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Sponsor type
Government

ROR
https://ror.org/02cq7de70

Funder(s)

Funder type
Government

Funder Name
Counties Manukau District Health Board (CMDHB) (New Zealand)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/11/2012		Yes	No