Participant Information Sheet

Title of Study: Clinical Evaluation of an Antibiotic Impregnated Catheter against Peritonitis

Short title: Catheter against peritonitis Study (CAP study)

Name of Researcher(s): Prof Maarten Taal (Chief Investigator); Prof Roger Bayston (Co-chief investigator); Dr Hari Dukka (Co-investigator), Dr Zoe Pittman (Co-investigator), Dr Katherine Belfield

We would like to invite you to take part in our research study. Before you decide we would like you to understand why the research is being done and what it would involve for you. One of our team will go through the information sheet with you and answer any questions you have. Talk to others about the study if you wish. Ask us if there is anything that is not clear.

In brief, the study team have developed a modification to a standard peritoneal dialysis (PD) catheter to introduce antibiotics into the material to potentially help to prevent infections. This study uses the modified PD catheter and is designed to test if the catheter is acceptable to patients and to collect data on infections. This information will help design a future trial testing the effectiveness of this modification against PD related infection. All participants will have the modified catheter and be followed up in the standard way but in addition we will ask you to complete some short questionnaires over a period of 6 months. After six months you will finish the study and continue with your normal care. If you think you might be interested, please continue to read through the rest of this participant information sheet and please do not hesitate to ask the study team any questions (details at the end).

What is the purpose of the study?

Peritoneal dialysis (PD) is a type of treatment for kidney failure. In order to perform PD, a silicone tube is placed in the abdomen, with one end staying inside the peritoneal cavity and the other end exiting through the skin. This is known as a PD catheter. Fluid is run into the abdomen via the catheter and then drained out again after 1-12 hours. This process is repeated multiple times per day. While the fluid is in the abdomen, toxins and other waste chemicals normally removed by the kidneys are absorbed into the fluid, and these are then removed when the fluid is drained out. In this way, PD partially replaces kidney function.

Sometimes bacteria get into the catheter and this can cause serious infections in the abdomen called peritonitis (infection of the fluid, abdominal cavity and the peritoneal membrane which aide the dialysis). Peritonitis can lead to severe pain and discomfort for patients, in some cases needing hospital admission and removal of the catheter. PD patients can also get exit site (where the PD catheter comes

out of the skin) or tunnel (between the skin and abdominal space) infections. These infections all need treatment with antibiotics and peritonitis is one of the most common causes of people having to stop PD and change to another form of dialysis that involves direct filtration of the blood (haemodialysis).

At present, the primary measures available to prevent PD catheter infections are a) careful hygiene when handling the catheter, and b) antibiotics. Despite these measures, PD peritonitis is still common happening about once in every two and a half years. It is therefore necessary to look for additional ways to reduce the risk of PD related infections.

The purpose of the present study is to investigate the tolerability acceptability and safety of peritoneal dialysis (PD) catheters that have had three different antibiotics introduced into the silicone of the catheter. This study is not designed to adequately test the theory that the addition of antibiotics to the PD catheter can, in combination with good hygiene practices, reduce infection rates but we will collect information related to infections to help us in designing a future trial looking at that question.

Why have I been invited?

You are being invited to take part because you have chosen to have peritoneal dialysis as treatment for your kidney failure. We will invite all similar patients who are starting PD or having a PD catheter replaced to participate in this study. We aim to recruit 40 participants over a period of 18 months. If you are pregnant (or planning to become pregnant) or are breast feeding, you cannot take part in this study as there is not adequate safety data on the antibiotics during pregnancy. If a participant were to become pregnant whilst in the study, we will closely monitor them until the end of the pregnancy.

Do I have to take part?

It is up to you to decide whether or not to take part. If you do decide to take part, you will be given this information sheet to keep and be asked to sign a consent form. If you decide to take part, you are still free to withdraw at any time and without giving a reason. This would not affect either your legal rights or the quality of your future medical care.

How do I let you know my decision to take part or not?

Once you have read and understand the Participant Information Sheet, and had sufficient time (at least 48 hours) to consider your decision regarding participation in this study, you may wish to contact us on 01332 788608 or email us dhft.derbykidneystudies@nhs.net to let us know your decision. The research team will telephone you once after 48 hours if no response has been received, to confirm your decision regarding participation in the research. There will be no further contact with you regarding this research if you do not wish to take part.

What will happen to me if I decide to take part?

After you have read and understood this Participant Information Sheet and had sufficient time (at least 48 hours) to consider your participation in this study, you will be invited to a meeting with one of the Study team who can answer any additional questions and go through the consent process for the study. We will ask you to sign a consent form, which shows you are willing to take part.

We anticipate that most participants will be given a date for the PD catheter insertion within 2 weeks of this process. During this time we will collect some basic information from your medical records about your age, ethnicity, medical conditions, medicines and results of routine blood tests.

All participants consenting to take part in this study will have a treated PD catheter that has had three antibiotics introduced into the silicone inserted in the usual manner and this will be explained in detail as a part of your medical care.

The procedure to place the PD catheter involves X-ray as per standard care, to ensure the catheter is placed safely and is in correct position. Any X-ray exposure can increase the risk of cancers many decades later. The estimated total research protocol dose is set at 0.5mSv. This is the equivalent of less than three months of UK background radiation. It would increase your risk of cancer by 0.0025% (compared to our natural risk of cancer of 50%). A small proportion of individuals will require a general anaesthetic and surgical PD catheter insertion and if that is the case you will have been informed of that by your usual kidney Dr's but if you are unclear if this applies to you, please ask.

After the PD catheter insertion your peritoneal dialysis nurse will check on your health and inspect the PD catheter according to our usual schedule of standard care on days 0, 3, 7, 10 and 13. Standard blood tests will be done on day 7. Each time you are seen or assessed by the PD team over the next 6 months will count as a study visit and we will collect information related to that visit. The information we collect broadly reflects the standard care you would receive if you were not involved in the study. We will however ask you to complete a short quality of life questionnaire and answer some short questions about the PD catheter and its acceptability. We will ask you to complete these questions on the day of insertion and at 7 days after you have completed your PD training as well as at 3 and 6 months on PD.

Your dialysis training will start as usual on day 13 after catheter insertion. A specialist peritoneal dialysis nurse will visit you at home on days 1 and 7 after completion of training, and you will also receive a phone call in between to check on your health.

After this initial period, you will receive monthly visits at home from your peritoneal dialysis nurse, which is part of the usual care of people on peritoneal dialysis. At each visit the nurse will inspect and photograph the catheter exit site and take blood samples for standard blood tests. If you develop an infection during the 6 months of the study either at the exit site of the PD catheter or peritonitis, you will be required to visit the hospital as part of standard care. The infection will be treated with antibiotics in the usual way. We will collect information about the infection and if an infection is confirmed then these microbiology (infection) samples will be sent for further analysis at the University of Nottingham. If your PD catheter gets removed for any reason during the 6 months of the active study this will also be analysed at the University of Nottingham. Once analysis of the removed catheter is complete, they will be destroyed by incineration.

Your participation in the study will continue for 6 months after the PD catheter was placed. After this time, you will continue to receive standard care from the peritoneal dialysis team. At the end of the study recruitment period the treated PD catheters will no longer be available for use. However, the antibiotic treated catheter will not be removed unless there are problems related to the catheter.

In the unlikely event of loss of your mental capacity, your participation would be withdrawn from the study. Identifiable data or tissue already collected with consent would be retained and used in the study. No further data or tissue would be collected, or any other research procedures carried out on or in relation future events.

Any data used for presentation purposes will be anonymised, ensuring participants cannot be identified. This includes any direct comments or quotes from participants recorded on the acceptability questionnaire.

The flow chart below summarises the study procedures. Area's highlighter in RED are additional to the standard care for individuals having a PD catheter inserted.

Participant Information Sheet given.

Written CAP study consent signed.

Day 0
PD catheter insertion
Information collected from medical records.
Quality of life and acceptability questionnaire

Follow-up visit post PD catheter insertion on day 3,7, and 10

- To ensure well being
- To begin PD care education
- To discuss any adverse effects
- Exit site review
- Routine blood test on day 7

Day 13 PD training begins.

- One to one training sessions tailored to need.

Initial follow up after completion of training.

- A nurse will visit on day 1, with a phone call on day 2 post training.
- Day 7 post training
  - Exit site review.
  - Quality of life and acceptability questionnaire

Follow up after completion of training.

- Monthly visits for exit site review and blood test Quality of life and acceptability questionnaire at 3 and 6 months

Expenses and payments

You will not be paid to participate in this study. All study visits will be done at the same time as your usual clinical care, so no extra visits will be required.

What are the possible disadvantages and risks of taking part?

This study involves placing a PD catheter which is a part of your routine clinical care. The only change is that the catheter is treated with antibiotics. There is a possibility that some people may have negative reactions to the antibiotic treated catheter, but we expect this will be uncommon. People with known allergies to the antibiotics added to the catheters will not be invited to participate in the study.

What are the possible benefits of taking part?

We cannot promise that the study will help you, but we hope the information we collect will help us to design larger studies to see if catheters treated with antibiotics will help reduce infections and the need for hospital admissions.

What if there is a problem?

If you are worried or have any questions about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions. The researchers contact details are given at the end of this information sheet.

If you want to speak to someone who is independent, or if you have any concerns or a complaint, you should contact the Patient Advisory and Liaison service (PALS) at:

Office:01332785156

Text: 07799337500

Email: uhdb.contactpalsderby@nhs.net

The normal NHS complaints mechanism will be available to you.

We do not expect it to, but in the event, something does go wrong and you are harmed, then you may have grounds for legal action, but you may have to pay your legal costs.

What tests and measurements will I need to do?

If you agree to participate in this study, you will have standard blood tests and inspections of the exit site at specified intervals. We will ask you to complete a questionnaire four times during the study period. You may need to visit hospital if you develop an infection, but this will be part of your routine clinical care.

How will we use information about you?

We will need to use some of your personal information for this research project. This personal information will include your name and contact details. People will use this information to do the research or to check your records to make sure that the research is being done properly. People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead. We will keep all personal information about you safe and secure.

Once we have finished the study, we will keep some of your information so that we can check the results. We will write our reports in such a way nobody will be able to work out that you took part in the study.

Any data used for presentation purposes will be anonymised, ensuring participants cannot be identified. This includes any direct comments or quotes from participants recorded on the acceptability questionnaire.

In the unlikely event of loss of your mental capacity, your participation would be withdrawn from the study. Identifiable data or tissue already collected with consent would be retained and used in the study. No further data or tissue would be collected, or any other research procedures carried out on or in relation to future events.

What are my choices about how my information is used?

You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have. If you choose to stop taking part in the study identifiable data or tissue already collected with consent would be retained and used in the study. No further data or tissue would be collected or any other research procedures carried out on or in relation to future events.

If you choose to stop taking part in the study, we will not remove the PD catheter unless there is a specific reason to do so, or you request this. We need to manage your records in specific ways for the research to be reliable. This means that we will not be able to change the information we hold about you. Research could go wrong if information is removed or changed.

Where can I find out more about how my information is used?

You can find out more about how we use your information:

- at https://www.uhdb.nhs.uk/research-how-we-use-your-information
- by asking one of the research team
- or by sending an email to uhdb.dataprotectionofficer@nhs.net
- You can also find general information about patient involvement in research from https://www.hra.nhs.uk/information-about-patients/

What will happen if I do not want to carry on with the study?

Your participation is voluntary, and you are free to withdraw at any time, without giving any reason, and without your legal rights being affected. If you withdraw then the information collected so far cannot be erased and that this information may still be used in the project analysis.

Involvement of the General Practitioner/Family doctor (GP)

Your GP will be informed about your involvement with your permission. If any of your test results require further action, your GP will also be informed.

What will happen to the results of the research study?

The results of this study will be submitted to scientific journals for publication. The results will also be presented at scientific conferences. You will not be identified in any publications or presentations. Participants will be informed of the results of the study via the departmental research newsletter, which is made available to all patients.

What happens to my research information after the study?

Once we have finished the study, the research team will keep the research information for a maximum of five years, in case we need to check it.

Once details like your name or NHS number have been removed, other researchers will not be able to contact you to ask you about future research. Any information that could show who you are will be held safely with strict limits on who can access it.

Who is organising and funding the research?

This study is being organised and sponsored by University Hospitals of Derby and Burton NHS Foundation Trust (UHDB) and University of Nottingham. Funding for the study is provided by the National Institute for Health Research (NIHR) Invention for Innovation (I4I) programme.

Who has reviewed the study?

All research in the NHS is looked at by several different bodies before it can start. This is to ensure that the study meets ethical and legal standards, and the safety, rights and well-being of participants are protected.

This trial has been reviewed and approved by:

- Research Ethics Committee, an independent group of experts and lay members.
- National Institute for Health Research.

Further information and contact details

Professor Maarten Taal

Professor of Medicine and Honorary Consultant Nephrologist

Department of Renal Medicine,

University Hospitals of Derby and Burton NHS Foundation Trust,

Royal Derby Hospital,

Uttoxeter Rd,

Derby,

DE22 3NE,

United Kingdom

Telephone: 01332 789344