ISRCTN26347295 https://doi.org/10.1186/ISRCTN26347295

# Evaluation of antibiotic-treated catheters to prevent peritonitis associated with peritoneal dialysis

**Submission date**
22/04/2024

**Recruitment status**
Recruiting

**Registration date**
20/06/2024

**Overall study status**
Ongoing

**Last Edited**
02/07/2024

**Condition category**
Urological and Genital Diseases

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

## Plain English summary of protocol

Background and study aims
Peritoneal dialysis (PD) is a type of dialysis that can be used to treat people with kidney failure. In order to perform PD, a silicone tube is placed with one end in the abdominal cavity and the other end exiting through the skin. Fluid is run through the abdomen through the tube and then drained out again after 1 to 4 hours. While the fluid is in the abdomen, toxins and other waste chemicals move from the body into the fluid and are then removed when the fluid is drained out. This process is repeated multiple times per day. In this way, PD partially replaces the kidney function.
Infection related to the tube is the most common risk associated with PD. This may be mild if it affects only the skin but can be severe if the infection spreads to the abdominal cavity. Infection in the abdominal cavity is called peritonitis and may cause severe pain and even life-threatening sepsis. Peritonitis requires urgent treatment with antibiotics and often admission to hospital. In severe cases the PD tube must be removed to treat the infection.
Currently, the only measures available to prevent PD tube infections are careful hygiene when handling the tube and antibiotics given before the tube is placed, or if there is any concern that the tube is contaminated.
Despite these measures, 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). Frequent use of antibiotics may also cause the bacteria that cause peritonitis to become resistant or cause other adverse events such as Clostridium difficile disease. In addition, peritonitis causes acute distress to the patient.
This study seeks to address the clinically important and costly problem of infections associated with PD. The cost of renal replacement therapy is expensive and consumes half of the £1.45 billion NHS budget for chronic kidney disease. The approximate cost for treatment of PD-associated peritonitis is £3,103 per episode.
This study proposes to test a PD catheter with three different antibiotics impregnated into the silicone. The catheter will be inserted into a person needing PD as part of their normal care. The focus of the study will be to check if the PD catheters are safe for use and more importantly acceptable to the patient. Clinical and pre-clinical studies of other devices using antimicrobial impregnation technology support its effectiveness. The formulation of the antimicrobial-

impregnated PD catheters is the same as the antimicrobial-impregnated urinary catheters that have already been tested for patient acceptability and tolerability in long-term catheter users. Results from a study of the antimicrobial urinary catheter suggest that the antibiotic formulation is biocompatible following human exposure for 84 days. The antimicrobial-impregnated PD catheter is also likely to be compatible with the delicate peritoneum. Silicone impregnated with rifampicin, tricoslan and trimethoprim using the same technology and implanted into the peritoneum of male rats did not show any difference in peritoneal membrane at 7 or 31 days after implantation compared to controls. There was no evidence of peritonitis or local inflammation.
One of the advantages of antimicrobial-impregnation technology is that the antimicrobials are embedded throughout the silicone rather than only on the surface. This allows the antimicrobial molecules to move freely within the silicone and are able to move to the catheter surface to replenish antimicrobials that have been rinsed away, maintaining a constant and high level of antimicrobial activity at the surface, the site of microorganism colonisation.

Who can participate?
Patients over the age of 18 years requiring PD dialysis

What does the study involve?
The study involves the insertion of a treated PD catheter at the same time point as a standard PD catheter would be inserted if not in the study and according to clinical need. Participants will receive the same number of visits and clinical care as routine. Their blood will be taken at each visit and the exit site of the PD catheter will be examined and photographed by a PD nurse, but in addition participants will also be asked to complete a questionnaire at the time of recruitment, 7 days after training and then at 3 and 6 months. There will be no additional study visits or tests but if a participant has the PD catheter removed or has a PD infection they will be asked to allow additional analysis of the PD fluid and PD catheter after removal to check for antibiotic resistance. Participants will be seen on days 0, 3, 7 and 10, just like standard patients. These visits may take place in the participant's home or the hospital outpatients department. On day 13 training begins for PD therapy. Once training has been completed, participants are visited at home to observe completing the therapy and will receive a phone call the following day to check if there are any problems. There is a further visit on day 7 after starting therapy (participants will be asked to complete a questionnaire). Patients are visited monthly or more frequently if there are any clinical concerns. At the end of the study (6 months) participants will continue with standard clinical care and monthly visits.

What are the possible benefits and risks of participating?
The possible benefit of participating is the reduction of PD infections that may require the removal of the PD catheter. Possible risks include exposure to radiation, but this will be at the same levels as those patients who receive standard care.

Where does the study run from?
University Hospitals of Derby and Burton NHS Foundation Trust (UHDB) (UK)

When is the study starting and how long is it expected to run for?
April 2021 to March 2026

Who is funding the study?
National Institute for Health and Care Research (UK)

Who is the main contact?
Prof. Maarten Taal, maarten.taal@nottingham.ac.uk

# Contact information

### Type(s)
Public, Scientific, Principal Investigator

### Contact name
Prof Maarten Taal

### ORCID ID
http://orcid.org/0000-0002-9065-212X

### Contact details
School of Medicine
University of Nottingham
Royal Derby Hospital Campus
Uttoxeter Road
Derby
United Kingdom
DE22 3DT
N/A
maarten.taal@nottingham.ac.uk

### Type(s)
Public, Scientific, Principal Investigator

### Contact name
Prof Roger Bayston

### ORCID ID
http://orcid.org/0000-0002-8312-3844

### Contact details
School of Medicine
University of Nottingham
Nottingham
United Kingdom
NG7 2UH
N/A
roger.bayston@nottingham.ac.uk

# Additional identifiers

### EudraCT/CTIS number
Nil known

### IRAS number
333587

### ClinicalTrials.gov number

Nil known

### Secondary identifying numbers
UHDB/2021/021, IRAS 333587, CPMS 59313

# Study information

### Scientific Title
Clinical evaluation of an antimicrobial-impregnated catheter against peritonitis: the Catheters Against Peritonitis (CAP) study

### Acronym
CAP

### Study objectives
Is a PD catheter impregnated with the antimicrobials rifampicin, sparfloxacin, and triclosan well-tolerated by patients and do the data support further studies of efficacy.

### Ethics approval required
Ethics approval required

### Ethics approval(s)
Approved 20/12/2023, Health Research Authority: North West - Manchester South Research Ethics Committee (Redmond Place, Stratford, E20 1JQ, United Kingdom; N/A; approvals@hra.nhs.uk), ref: 23/NW/0340

### Study design
Single-centre interventional non-randomized feasibility study

### Primary study design
Interventional

### Secondary study design
Non randomised study

### Study setting(s)
Hospital

### Study type(s)
Efficacy

### Participant information sheet
See study outputs table

### Health condition(s) or problem(s) studied
Adults who opt for peritoneal dialysis and therefore require the insertion of a peritoneal dialysis catheter

### Interventions

Eligible individuals who have already chosen PD as their preferred renal replacement therapy will be offered the choice to take part in the trial.

All participants will have the treated PD catheter inserted at the same point as a standard PD catheter would be inserted if not in the trial and according to clinical need.

Participants will receive the same visits and clinical care as routine but in addition will be asked to complete a questionnaire at the time of recruitment, at 7 days post training and then at 3 and 6 months. The questionnaire is expected to take between 5 and 15 minutes to complete.

There will be no additional visits or tests but if a participant has the PD catheter removed or has a PD infection they will be asked to undergo additional analysis of the PD fluid and PD catheter after removal to check for drug resistance.

As a standard patients having a PD tube inserted will be seen at days 0, 3, 7, and 10. Some of these visits are in the patient's own home and some in the hospital outpatients department. On day 13 training begins for PD therapy. Once training is complete (2 - 5 days on average) patients are visited at home and observed completing the therapy and will receive a phone call the following day to check if there are any problems. There is a further visit on day 7 after start starting therapy (when trial participants will be asked to complete a short questionnaire). Patients are then visited monthly or more frequently if there are clinical concerns.

At the end of the study (6 months) participants continue with standard clinical care and monthly visits.

## Intervention Type
Mixed

## Primary outcome measure
Safety and tolerability of an antimicrobial-impregnated catheter, measured using the rate of adverse events to the antimicrobials or the impregnation process encountered by PD patients during 6 months of observation

## Secondary outcome measures
1. Patient acceptability determined by modified Integrated Palliative Care Outcome Scale (IPOS) Renal questionnaire and patient acceptability questionnaire at baseline, 3 weeks, 3 months and 6 months.
2. Peritoneal dialysis-related infections: PD peritonitis, exit site/tunnel infection identified and defined using local protocols and International Society for Peritoneal Dialysis Guidelines; microorganism antibiotic resistance profile of organisms causing catheter-related infections colonisation of PD catheters removed within the study period, measured using clinical assessment and laboratory culture techniques during 6 months of observation.
3. Technique failure: transfer from peritoneal dialysis to hemodialysis measured using clinical records and observation during 6 months of observation.

## Overall study start date
01/04/2021

## Completion date
31/03/2026

# Eligibility

### Key inclusion criteria
1. Aged 18 years or older
2. End-stage kidney disease of any cause
3. Elective PD catheter insertion

### Participant type(s)
Patient

### Age group
Adult

### Lower age limit
18 Years

### Upper age limit
100 Years

### Sex
Both

### Target number of participants
40

### Key exclusion criteria
1. Documented allergy to rifampicin, sparfloxaxacin (or any fluoroquinolone), triclosan, or silicone
2. Pregnant, likely to become pregnant, or breastfeeding
3. Emergency PD catheter insertion

### Date of first enrolment
31/03/2024

### Date of final enrolment
30/09/2025

# Locations

### Countries of recruitment
England

United Kingdom

### Study participating centre
**University Hospitals of Derby and Burton NHS Foundation Trust**
Royal Derby Hospital
Uttoxeter Road

Derby
United Kingdom
DE22 3NE

# Sponsor information

### Organisation
University Hospitals of Derby and Burton NHS Foundation Trust

### Sponsor details
Uttoxeter Road
Derby
England
United Kingdom
DE22 3DT
N/A
UHDB.sponsor@nhs.net

### Sponsor type
Hospital/treatment centre

### Website
https://www.uhdb.nhs.uk/

### ROR
https://ror.org/04w8sxm43

# Funder(s)

### Funder type
Government

### Funder Name
National Institute for Health and Care Research

### Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

### Funding Body Type
Government organisation

### Funding Body Subtype
National government

### Location
United Kingdom

# Results and Publications

### Publication and dissemination plan
Results of the study will be submitted to high impact peer-reviewed journals for publication, including open access journal as soon as data analysis is completed. the results will also be presented at conferences. Patients will be informed of the results of the study via a departmental research newsletter, which will be made available to all patients

### Intention to publish date
31/03/2027

### Individual participant data (IPD) sharing plan
The datasets generated during/and or analysed during the current study will be stored in a non-publicly available repository. They will be stored in a password-protected file on a secure server (University Hospitals of Derby and Burton NHS Foundation Trust).
The datasets generated and/or analysed during the current study will be available on request from the Sponsor, University Hospitals of Derby and Burton NHS Foundation Trust (UHDB.sponsor@nhs.net).

### IPD sharing plan summary
Stored in non-publicly available repository, Available on request

### Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Participant information sheet | version 1.1 | 07/12/2023 | 07/05/2024 | No | Yes |
| Protocol file | version 1.0 | 09/12/2023 | 07/05/2024 | No | No |