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# Pelvic floor symptoms in women receiving peritoneal dialysis

**Submission date**
27/05/2025

**Recruitment status**
Recruiting

**Registration date**
05/06/2025

**Overall study status**
Ongoing

**Last Edited**
05/06/2025

**Condition category**
Urological and Genital Diseases

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

## Plain English summary of protocol

Background and study aims
Peritoneal dialysis is normally carried out at home. This gives the person some flexibility over work, study, and other activities. Because peritoneal dialysis involves the dwelling and exchange of dialysis fluid within the abdomen, the increased pressure may lead to problems in the pelvic floor muscles, such as pelvic floor prolapse. Such problems may be more common in women who have given birth, are or have been overweight.
The pelvic floor is made up of muscles that form a sling from the front to the back to the back of the pelvis. They provide support to the organs within the pelvis and play a role in controlling your bladder, bowel and sexual functions. Pelvic floor prolapse refers to a bulging of bowel, bladder or womb into or outside of the vagina. There have been a few reports of this problem in women who receive peritoneal dialysis. However, we do not know how common it is or how it affects daily living.
The aim of this pilot study is to test questionnaires in women receiving peritoneal dialysis, which ask about pelvic floor symptoms. The information we receive will help us with the design of a larger study.

Who can participate?
Women aged between 18 and 90 years who are receiving peritoneal dialysis

What does the study involve?
The study involves completing questionnaires that ask about the presence of pelvic floor symptoms and how they affect daily life. These will be completed at the start of the study and after 6 months.

What are the possible benefits and risks of participating?
While we do not expect that there will be direct health benefits, symptoms or other health issues may be identified from completing the questionnaires. The doctor will be informed so that treatment or referral for help can be arranged.
The risk is that the study questionnaires may touch on sensitive topics. Psychological support will be provided where there is distress as a result of participating in the study.

Where is the study run from?
University Hospitals of Leicester NHS Trust (UK)

When is the study starting and how long is it expected to run for?
April 2025 to September 2026

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Dr Osasuyi Iyasere, osasuyi.iyasere@nhs.net

# Contact information

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

### Contact name
Dr Osasuyi Iyasere

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# Additional identifiers

### Clinical Trials Information System (CTIS)
Nil known

### Integrated Research Application System (IRAS)
352200

### Protocol serial number
EDGE ID - 176516

# Study information

### Scientific Title
Exploring pelvic floor symptoms in women receiving peritoneal dialysis – a pilot observational study

### Acronym
EXPLORE PD

### Study objectives
It is feasible to evaluate pelvic floor dysfunction in women receiving peritoneal dialysis (PD)

### Ethics approval required
Ethics approval required

### Ethics approval(s)
approved 07/04/2025, Health and Social Care Research Ethics Committee A (HSC REC A) (Business Services Organisation Unit 4, Lissue Industrial Estate West Rathdown Walk Moira Road Lisburn BT28 2RF, Lisburn, BT28 2RF, United Kingdom; +44 (0)28 95 361404; RECA@hscni.net), ref: 25/NI/0046

### Study design
Pilot single-centre prospective cohort study

### Primary study design
Observational

### Study type(s)
Quality of life

### Health condition(s) or problem(s) studied
Pelvic floor symptoms in women on peritoneal dialysis

### Interventions
Pelvic floor questionnaires that examine the burden and impact of pelvic floor symptoms will be administered to eligible at baseline and after 6 months. Demographic and clinical data will also be captured during the study period.

### Intervention Type
Other

### Primary outcome(s)
1. Study recruitment rate measured as a percentage at baseline
2. Study dropout rate measured as a percentage over 6 months follow-up
3. Questionnaire completion rates measured as pa ercentage at baseline and 6 months

### Key secondary outcome(s))
1. Pelvic floor symptoms measured using the Pelvic Floor Distress Inventory (PDFI-20) at baseline and 6 months
2. Impact of pelvic floor symptoms on wellbeing measured using the Pelvic Floor Impact Questionnaire (PFIQ-7) scores at baseline and 6 months

### Completion date
30/09/2026

## Eligibility

### Key inclusion criteria
1. Aged between 18 and 90 years
2. Receiving peritoneal dialysis
3. Female
4. Able to provide informed consent

### Participant type(s)
Patient

### Healthy volunteers allowed
No

### Age group
Adult

### Lower age limit
18 years

### Upper age limit
90 years

### Sex
Female

### Key exclusion criteria
1. Unable to provide informed consent
2. Any other significant disease or disorder which, in the opinion of the patient's own clinician, may put the participants at risk because of participation in the study. For example, a severe mental health disorder or recent bereavement

### Date of first enrolment
15/05/2025

### Date of final enrolment
30/04/2026

## Locations

### Countries of recruitment
United Kingdom

England

### Study participating centre
**University Hospitals of Leicester NHS Trust**
Leicester Royal Infirmary
Infirmary Square
Leicester

United Kingdom
LE1 5WW

# Sponsor information

**Organisation**
University Hospitals of Leicester NHS Trust

**ROR**
https://ror.org/02fha3693

# Funder(s)

**Funder type**
Other

**Funder Name**
Investigator initiated and funded

# Results and Publications

**Individual participant data (IPD) sharing plan**
The datasets generated during and/or analysed during the current study will be available upon request from Dr Osasuyi Iyasere (osasuyi.iyasere@nhs.net)

**IPD sharing plan summary**
Available on request