

Can bladder health predict kidney transplant success?

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|--------------------------|---------------------------------|---|
| Submission date | Recruitment status | <input checked="" type="checkbox"/> Prospectively registered |
| 06/01/2026 | Not yet recruiting | <input checked="" type="checkbox"/> Protocol |
| Registration date | Overall study status | <input type="checkbox"/> Statistical analysis plan |
| 22/01/2026 | Ongoing | <input type="checkbox"/> Results |
| Last Edited | Condition category | <input type="checkbox"/> Individual participant data |
| 22/01/2026 | Urological and Genital Diseases | <input checked="" type="checkbox"/> Record updated in last year |

Plain English summary of protocol

Background and study aims

Many patients with kidney failure need a kidney transplant. Some of these patients will have problems relating to the storage or passage of urine. In many cases, this is unrecognized before transplant, especially if the patient no longer passes urine. This can lead to problems after the transplant, resulting in infections, complications and poor kidney function. There are very few studies which have looked at how issues with the patient's urinary tract and bladder affect the outcome of a kidney transplant. However, it's well-recognized amongst kidney transplant surgeons to be a significant problem. This study aims to determine the number of patients who have undiagnosed waterworks issues before transplant and investigate if these issues make it more likely for the patient to have urinary tract infections, poor kidney transplant function or other complications in the year following transplant.

Who can participate?

Patients having a kidney transplant in Glasgow, UK.

What does the study involve?

Everyone will be approached within two years: both when they join the transplant waiting list and when they receive a transplant. Patients will be followed up at 6 weeks and 1 year after transplant, taking measures of bladder function from history, questionnaires and simple studies of urine flow/ bladder function.

What are the possible benefits and risks of participating?

Currently, there is no standardized suggested work-up of the bladder and urinary tract prior to a kidney transplant. Different transplant centers do different things and there is no agreed-upon best approach. The results from this study might better inform how and why a patient's lower urinary tract should be assessed before transplant. This information will hopefully reduce complications and improve outcomes after transplant. If the study identifies problems pre-transplant that predict complications after transplant, it is hoped that the results of this study could inform a larger study in the future that could intervene on these issues pre-transplant to see if it prevents complications in the future. However, at the moment, what to measure or how best to intervene is not known. It's hoped that this study will help us better understand these issues.

If a catheter insertion is needed to fill the bladder, there may be some mild discomfort on catheter insertion. There is a very small risk of introducing infection.

Where is the study run from?

Glasgow Renal Transplant Unit, Queen Elizabeth University Hospital, UK.

When is the study starting and how long is it expected to run for?

March 2026 to March 2031.

Who is funding the study?

NHS Greater Glasgow and Clyde, UK.

Who is the main contact?

Prof David Kingmore, david.kingmore@ggc.scot.nhs.uk

Contact information

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Integrated Research Application System (IRAS)

367244

Study information

Scientific Title

A longitudinal cohort study of urological complications predictable by pre-transplant lower urinary tract symptoms

Acronym

SCOPE

Study objectives

1. Primary objectives:

- To evaluate the association between pre-transplant Lower urinary tract symptoms (LUTS) with post-transplant urological complications. These will include Acute urinary retention, recurrent UTIs, ureteric strictures and leaks, urosepsis, and need for surgical/radiological intervention for urological causes.

2. Secondary objectives:

- To evaluate how the presence of moderate-severe LUTS impacts graft outcomes in the immediate 12 months following transplantation
- To determine if duration of time on the transplant waiting list and/ or anuria predict objective change in LUTS or adverse urological outcomes post-transplant
- To determine the change in LUTS post-renal transplantation.
- Decline in kidney function (transient/ permanent) due to urological causes

Ethics approval required

Ethics approval required

Ethics approval(s)

notYetSubmitted

Primary study design

Observational

Secondary study design

Longitudinal study

Study type(s)**Health condition(s) or problem(s) studied**

Kidney transplant, lower urinary tract symptoms, urological complications

Interventions

Patients will be recruited over two years and followed up until they are one year post-transplant, removed from the transplant waiting list or have died. All patients at the time of transplant and at the time of transplant wait-listing will be approached to offer participation. History, examination and all perioperative follow-up will be conducted as would be standard of care. Patients will be recruited in two phases:

- PHASE 1 (enrolled at transplantation): Evaluation of patients beginning on the day of transplant, prospectively at 6 weeks and 1 year
- PHASE 2 (enrolled at waitlisting): Evaluation of patients at time of waitlisting, prospectively 1-year post-waitlisting (if not yet transplanted), on day of transplant and at 6 weeks and 1-year post-transplant

All patients will undergo baseline assessment with history, examination, questionnaires (IPSS for males and ICIQ-FLUTS for females), along with Uroflowmetry and post-void residual assessment. For patients who do not produce enough urine for conclusive results (≥ 130 ml), a small filling catheter will be used to instil saline, and repeat assessment will be conducted. This will be limited to 300ml, without pressure testing and does not constitute/implies invasive urodynamic testing.

These assessments, along with review of medical notes, will be performed at the time of transplant listing (Phase 2), after 1 year on the transplant waiting list (Phase 1), on the day of transplant, 6 weeks and 12 months after transplantation.

Intervention Type

Other

Primary outcome(s)

1. Urological complications measured using a medical notes review for (acute urinary retention, recurrent UTIs, urine leak, ureteric strictures, urinary sepsis episodes, need of surgical/radiological intervention for urological cause) at one year post renal-transplant

Key secondary outcome(s)

1. Association between time on transplant waiting list, anuria status, and post-transplant LUTS and urological outcomes measured using a medical notes review at one year post renal-transplant

2. Lower urinary tract symptoms measured using the International Prostate Symptom Score (IPSS) for males, and the International Consultation on Incontinence Questionnaire Female

Lower Urinary Tract Symptoms Modules (ICIQ-FLUTS) for females at one year post renal-transplant

3. Graft survival measured using a medical notes review at one year post renal-transplant
4. Decline in Renal function due to urological cause measured using a medical notes review (eGFR, creatinine) at one year post renal-transplant

Completion date

10/03/2031

Eligibility

Key inclusion criteria

1. Adult patients (18 years of age or older) scheduled to undergo first-time renal transplantation (both deceased and living donor candidates)
2. Able to give informed written consent to participate

Healthy volunteers allowed

No

Age group

Mixed

Lower age limit

18 years

Upper age limit

100 years

Sex

All

Total final enrolment

0

Key exclusion criteria

1. Unable or unwilling to provide consent
2. Patients undergoing re-transplant
3. Patients undergoing simultaneous urological reconstructive procedures
4. Patients with previously reconstructed bladders (includes Augmentation cystoplasty, ileal conduit, neobladder etc.)
5. Significant cognitive impairment, which would limit their capacity to accurately report symptoms

Date of first enrolment

04/03/2026

Date of final enrolment

04/03/2030

Locations

Countries of recruitment

United Kingdom

Scotland

Study participating centre

NHS Greater Glasgow and Clyde

J B Russell House

Gartnavel Royal Hospital

1055 Great Western Road Glasgow

Glasgow

Scotland

G12 0XH

Sponsor information

Organisation

NHS Greater Glasgow and Clyde

ROR

<https://ror.org/05kdz4d87>

Funder(s)

Funder type

Funder Name

NHS Greater Glasgow and Clyde

Alternative Name(s)

Funding Body Type

Government organisation

Funding Body Subtype

Local government

Location

United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Data sharing statement to be made available at a later date

Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|--|-------------|--------------|------------|----------------|-----------------|
| <u>Other files</u> | version 1.1 | 08/12/2025 | 07/01/2026 | No | No |
| <u>Participant information sheet</u> | version 1.1 | 08/12/2025 | 07/01/2026 | No | Yes |
| <u>Participant information sheet</u> | version 1.1 | 08/12/2025 | 07/01/2026 | No | Yes |
| <u>Protocol file</u> | version 1.4 | 09/12/2025 | 07/01/2026 | No | No |