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Can bladder health predict kidney transplant success?

Submission date
06/01/2026

Recruitment status
Recruiting

Registration date
22/01/2026

Overall study status
Ongoing

Last Edited
17/11/2026

Condition category
Urological and Genital Diseases

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] 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?
Adult patients undergoing their first kidney transplant in Glasgow, UK.

What does the study involve?
Everyone will be approached in 2 phases: Phase 1: when they are invited to receive their transplant; Phase 2: when they are joining the waiting list to receive the 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?
July 2026 to July 2031

Who is funding the study?
University of Glasgow, UK.
The Urology Foundation (small projects fund), UK.

Who is the main contact?
Prof David Kingmore, david.kingmore@ggc.scot.nhs.uk
Ms Emma Aitken, Emma.Aitken10@nhs.scot

Contact information

Type(s)
Principal investigator

Contact name
Prof David Kingsmore

Contact details
Glasgow Renal Transplant Unit,
Queen Elizabeth University Hospital,
1345 Govan Rd
Glasgow
United Kingdom
G51 4TF
+44 0141 451 6209
david.kingmore@ggc.scot.nhs.uk

Type(s)
Scientific

Contact name
Miss Emma Aitken

Contact details
Glasgow Renal Transplant Unit,
Queen Elizabeth University Hospital,
1345 Govan Rd
Glasgow
United Kingdom
G51 4TF
+44 0141 451 6209
emma.aitken10@nhs.scot

Type(s)
Public

Contact name
Mr Dhruv Satya Sahni

Contact details
Glasgow Renal Transplant Unit,
Queen Elizabeth University Hospital,
1345 Govan Rd
Glasgow
United Kingdom
G51 4TF
+44 0141 451 6209
Dhruv.Sahni@glasgow.ac.uk

Additional identifiers

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
Current study objectives as of 17/11/2026:
Primary objectives:
To describe the distribution of pre-transplant lower urinary tract symptom scores and objective voiding parameters in adults undergoing for their first RT.
This will be assessed using IPSS for male participants and ICIQ-FLUTS for female participants supplemented by uroflowmetry and PVR assessment, with non-assessable measurements explicitly reported.

Secondary objectives:
To explore associations between pre-transplant lower urinary tract characteristics and urological complications occurring within 12 months following transplantation.
“Urological complication” will be a composite any one/ more of the following:
1. Urinary retention, defined as documented failure to void or clinically significant incomplete bladder emptying (PVR ≥ 150mLs as per departmental protocol) requiring indwelling catheterisation or clean intermittent catheterisation
2. Recurrent culture-proven urinary tract infections, defined as 2 or more in the first 6 months/ 3 or more in the first 12 months post-transplant. Distinct episodes will require documented clinical resolution of the preceding infection followed by a subsequent symptomatic, culture-positive episode. Positive urine cultures without symptoms will not, in isolation, constitute symptomatic

UTI.
3. Ureteric leak or stricture proven on imaging
4. Sepsis of urinary source requiring hospital admission
5. Any patient undergoing any surgical or radiological intervention for a urological complication (excluding routine stent removal post-transplant)
6. Graft loss as a result to urological complications within the first year of transplantation

Additional secondary objectives include:
1. To explore relationship between LUT assessment and subsequent graft function
2. Longitudinal changes in LUTS scores, voiding parameters and QOL at 6 weeks and 1 year post RT
3. Explore whether the duration of time on the transplant waiting list and/ anuria predict objective change in LUTS or adverse urological outcomes post-transplant [Phase 2]

Previous 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)
Approved 14/07/2026, South Central- Oxford A Research Ethics Committee (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 02071048241; oxforda.rec@hra.nhs.uk), ref: 26/SC/0213

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
Current methodology as of 17/11/2026:
SCOPE comprises two discrete recruitment pathways within a single prospective observational

cohort:
1. Phase I: Those approached for consent on admission for potential/ scheduled renal transplant
2. Phase II: Those approached for consent at time of transplant waitlisting.

Patients can only be enrolled in the study once, thus are only eligible to participate in phase 1 or phase 2 (notably, the protocol for phase 2 is almost identical to phase 1, with additional study visits).

Both phases of the trial will run concurrently with recruitment commencing July 2026. It is anticipated that recruitment will take 12-18 months with 12-month follow-up post-transplantation. It is therefore anticipated that phase 1 will complete in Autumn 2028. The timing of deceased donor transplantation is unpredictable with patients spending variable lengths of time on the transplant waiting list; therefore, total duration of full-up required for phase 2 is less defined.

The average waiting time for renal transplantation in the UK is 547 days, therefore an absolute follow-up date of 31st December 2031 has been imposed for phase 2. By this time, we anticipate that most of the enrolled patients will have been transplanted.

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 (based on volume and habitual voids/ historical uroflowmetry), a small filling catheter (10Fr) will be used to instil saline, and repeat assessment will be conducted. This will be limited to 250ml, without pressure testing and does not constitute/imply invasive urodynamic testing.

All patients will be assessed on day of transplantation, 6 weeks (+/-2 weeks) post-transplant and 12 months (+/- 4 weeks) post-transplant. Additionally, patients in phase 2 will be assessed at time of waiting listing and (if still on the waiting list) at 12 months post-listing. All study visits will correspond to clinical visits undertaken as part of routine follow-up per departmental protocols.

Previous methodology:
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/imply 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 distribution of pre-transplant lower urinary tract symptom scores measured using the International Prostate Symptom Score (IPSS) in men and the International Consultation on Incontinence Questionnaire Female Lower Urinary Tract Symptoms (ICIQ-FLUTS) in women at pre-transplant

Previous primary outcome as of 17/11/2026:
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. Associations between pre-transplant lower urinary tract characteristics and urological complications occurring within 12 months following transplantation measured using measured using “urological complication” that will be a composite of any one/more of the following: urinary retention, defined as documented failure to void or clinically significant incomplete bladder emptying (PVR > 150mLs as per departmental protocol) requiring indwelling catheterisation or clean intermittent catheterisation; recurrent culture-proven urinary tract infections, defined as 2 or more in the first 6 months/ 3 or more in the first 12 months post-transplant (distinct episodes will require documented clinical resolution of the preceding infection followed by a subsequent symptomatic, culture-positive episode, positive urine cultures without symptoms will not, in isolation, constitute symptomatic UTI; ureteric leak or stricture proven on imaging; sepsis of urinary source requiring hospital admission; any patient undergoing any surgical or radiological intervention for a urological complication (excluding routine stent removal post-transplant); and graft loss as a result to urological complications within the first year of transplantation, at 12 months

2. LUT assessment associations with subsequent graft function measured using creatinine and eGFR levels using the CKD-EPI equation at 12 months

3. Longitudinal changes in lower urinary tract symptoms (LUTS), voiding function and quality of life (QoL) measured using the International Prostate Symptom Score (IPSS) in men, the International Consultation on Incontinence Questionnaire Female Lower Urinary Tract Symptoms (ICIQ-FLUTS) in women, uroflowmetry parameters and post-void residual (PVR) volume at 6 weeks and 12 months after radiotherapy (RT)

4. Whether duration on the transplant waiting list and/or anuria predict changes in lower urinary tract symptoms (LUTS) or adverse urological outcomes after transplantation, measured using the International Prostate Symptom Score (IPSS) in men, the International Consultation on Incontinence Questionnaire Female Lower Urinary Tract Symptoms (ICIQ-FLUTS) in women, uroflowmetry parameters and post-void residual (PVR) volume at 12 months following Phase 2 recruitment

Previous primary outcome as of 17/11/2026:
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
31/07/2031

Eligibility

Key inclusion criteria
Current key inclusion criteria as of 17/11/2026:
1. All adult patients (18 years or older) scheduled/ waitlisted to undergo first renal transplantation
2. Able to give informed written consent to participate

Previous key inclusion criteria as of 23/07/2026:
1. Adult patients (18 years of age or older) scheduled to undergo renal transplantation (both deceased and living donor candidates)
2. Able to give informed written consent to participate

Previous 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 that would limit their capacity to accurately report symptoms

Date of first enrolment
20/07/2026

Date of final enrolment
31/07/2030

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
University of Glasgow

ROR
https://ror.org/00vtgdb53

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

Funder Name
Urology Foundation

Alternative Name(s)
The Urology Foundation (TUF), TUF

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

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?
Other files	version 1.1	08/12/2025	07/01/2026	No	No
Other files	version 1.0	02/06/2026	23/07/2026	No	No
Other files	version 1.1	07/07/2026	23/07/2026	No	No
Participant information sheet	version 1.1	08/12/2025	07/01/2026	No	Yes

Participant information sheet	version 1.1	08/12/2025	07/01/2026	No	Yes
Participant information sheet	version 1.1	07/07/2026	23/07/2026	No	Yes
Protocol file	version 1.4	09/12/2025	07/01/2026	No	No
Protocol file	version 1.0	02/06/2026	23/07/2026	No	No