

# Transplant ureteric stent removal: early versus standard removal

<b>Submission date</b> 17/02/2010	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered
<b>Registration date</b> 22/04/2010	<b>Overall study status</b> Completed	<input checked="" type="checkbox"/> Protocol
<b>Last Edited</b> 13/02/2017	<b>Condition category</b> Urological and Genital Diseases	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

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## Additional identifiers

## Study information

**Scientific Title**  
Transplant ureteric stent removal: early versus standard removal - a randomised controlled trial

**Acronym**  
TrUST

**Study objectives**

During kidney transplantation a plastic tube (stent) is placed in the transplant ureter, between the renal pelvis and the bladder. Meta-analyses of randomised controlled trials on the use of transplant ureteric stents (TUS) have shown that routine use of a TUS reduces major post-transplant urological complications, particularly urinary leaks and ureteric stenosis. However stent complications occur in around 20% of patients, both adults and children. Studies suggest that TUS complications; which include urine infection, stent migration and pain; are related to the time stents remain in-situ.

The optimum timing for stent removal is currently not known, however recent studies suggest that stents should be removed at 2 to 4 weeks post-transplantation. In our centre we have reduced the time that our ureteric stents remain in-situ from 12 to 6 weeks post-transplant on the basis of internal audit of transplant stent complications. Nevertheless, we continue to observe a 15 - 20% post transplant ureteric stent complication rate. We currently remove the stent using cystoscopy and to minimise associated risks do not advocate routinely performing the procedure before 6 weeks post-transplantation.

A new technique of suturing the ureteric stent to the urethral catheter was described in 1998. This technique allows early removal of both the stent and urethral catheter together without the need for cystoscopy. We hypothesise that this new technique would enable us to remove the stent at an earlier date and reduce the complication rate associated to ureteric stents in-situ for prolonged periods.

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

London Research Ethics Committee (REC), 27/01/2010, ref: 10/H0718/5

### **Primary study design**

Interventional

### **Study design**

Randomised controlled trial

### **Study type(s)**

Treatment

### **Health condition(s) or problem(s) studied**

Urological issues in renal transplants

### **Interventions**

There are two potential study arms to which patients are allocated:

Group 1: Standard technique for Transplant Ureteric Stent removal (sTUSr), or

Group 2: New technique with early Transplant Ureteric Stent removal (eTUSr)

A TUS is placed at the time of surgery along with a urinary catheter in all patients. Patients in the standard arm (Group 1) will have the urinary catheter removed on the ward on the 5th post-operative day. They will then undergo a cystoscopy, under either local or general anaesthetic, at week 6 to remove the TUS. Patients in the trial arm (Group 2) will have the TUS attached to the urinary catheter at the time of surgery. These patients will have the urinary catheter removed on the ward on the 5th post-operative day in the standard way. As the TUS is attached to the

catheter it will be removed at the same time as removal of the catheter. This group therefore do not require cystoscopy.

The study will be performed prospectively. Patients that require kidney transplantation will be recruited and allocated to a study arm. Participants of the study will be followed up in the same way as non-participants. A diary card will be completed by those in group 1 on the day of their cystoscopy. Stent related symptom assessment and quality of life questionnaires will be completed by all participants at week 1 and week 6. Data will be collected on all participants regarding ureteric complications, stent related complications, health economics and patient quality of life assessments for 3 months post-transplantation. Complications of ureteric stenosis will monitored for up to 6 months post-transplantation.

### **Intervention Type**

Procedure/Surgery

### **Primary outcome(s)**

Stent-related complications, specifically urinary infection, pain and migration. Information collected at each OP visit for 3 months.

### **Key secondary outcome(s)**

1. Rate of transplant ureteric leak or stenosis: information collected at each OP visit for up to 6 months
2. Patient acceptability, measured with quality of life questionnaires at week 1 and week 6
3. Economic costs (hospital and patient): Patient diary card on day of stent removal, hospital costs can be evaluated at 6 months

### **Completion date**

15/12/2015

## **Eligibility**

### **Key inclusion criteria**

1. Children aged 2 - 16 years, either sex
2. Adults aged 17 - 75 years, either sex
3. Needing kidney transplant

### **Participant type(s)**

Patient

### **Healthy volunteers allowed**

No

### **Age group**

Mixed

### **Sex**

All

### **Key exclusion criteria**

1. Urinary Tract exclusion:
  - 1.1. Urinary diversion e.g. ileal conduit, cutaneous ureterostomy, mitrofanoff
  - 1.2. Duplex transplant ureter
  - 1.3. Pelviureteric junction obstruction
  - 1.4. Surgical concern regarding the vascularity of the transplant ureter
  - 1.5. Donor kidney stone and use of bench (ex-vivo) ureteroscopy
  - 1.6. Early use of mammalian target of rapamycin (mTOR) inhibitors (early use is very uncommon as the drug has well documented concerns regarding worse tissue healing)
2. Risk of bleeding:
  - 2.1. Kidney capsule removed at retrieval
  - 2.2. Need for post-operative systemic heparinisation
  - 2.3. Greater than 3 cycles of pre-operative plasma exchange (DFFP) as part of transplant desensitisation program
3. Simultaneous kidney and pancreas transplant (SPK)

**Date of first enrolment**

27/05/2010

**Date of final enrolment**

22/11/2013

## **Locations**

**Countries of recruitment**

United Kingdom

England

**Study participating centre**

**Guy's Hospital**

London

United Kingdom

SE1 9RT

## **Sponsor information**

**Organisation**

Guy's and St Thomas' NHS Foundation Trust (UK)

**ROR**

<https://ror.org/00j161312>

## **Funder(s)**

## Funder type

Government

## Funder Name

National Institute for Health Research (NIHR) (UK) - Research for Patient Benefit (RfPB) Programme (ref: PB-PG-0909-20047) - grant pending, outcome due July 2010

# Results and Publications

## Individual participant data (IPD) sharing plan

### IPD sharing plan summary

Not provided at time of registration

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	01/08/2017		Yes	No
<a href="#">Protocol file</a>	version v2	14/12/2010	28/09/2016	No	No