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Transplant ureteric stent removal: early versus standard removal

Submission date	Recruitment status	[X] Prospectively registered
17/02/2010	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
22/04/2010	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
13/02/2017	Urological and Genital Diseases	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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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

Study design
Randomised controlled trial

Primary study design
Interventional

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
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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?
Results article	results	01/08/2017		Yes	No
Protocol file	version v2	14/12/2010	28/09/2016	No	No