

Transplant ureteric stent removal: early versus standard removal

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Mr Jonathon Olsburgh

Contact details
Guy's Hospital
6th Floor Renal Offices
St Thomas Street
London
United Kingdom
SE1 9RT

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

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

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use the contact details to request a patient information sheet

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 be monitored for up to 6 months post-transplantation.

Intervention Type

Procedure/Surgery

Primary outcome measure

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

Secondary outcome measures

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

Overall study start date

01/04/2010

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

Age group

Mixed

Sex

Both

Target number of participants

88 patients per group (176 patients in total)

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**

England

United Kingdom

Study participating centre

Guy's Hospital
London

United Kingdom
SE1 9RT

Sponsor information

Organisation

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

Sponsor details

c/o Jennifer Boston
Guy's Hospital
2nd Floor Conybeare House
St Thomas Street
London
England
United Kingdom
SE1 9RT
+44 (0)20 7188 5736
Jennifer.boston@gstt.nhs.uk

Sponsor type

Hospital/treatment centre

Website

<http://www.guysandstthomas.nhs.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

Publication and dissemination plan

The results are expected to be published in early 2016

Intention to publish date

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