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Randomised controlled trial of early versus late ureteric stent removal post kidney transplant

Submission date
26/10/2014

Recruitment status
No longer recruiting

Registration date
12/12/2014

Overall study status
Completed

Last Edited
12/12/2014

Condition category
Urological and Genital Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
This is a study to compare the number of urinary tract infections and urological complications among people that have had different treatments after having a kidney transplant. During the kidney transplant operation, patients have a stent (a thin hollow plastic tube) inserted into the ureter, the tube connecting the transplanted kidney to the bladder. This stent protects the surgical connection between the kidney and bladder. It is current practice to remove the stent 4-6 weeks after the transplant by inserting a flexible camera via the urethra into the bladder (known as flexible cystoscopy). There is some evidence that stents can increase the likelihood of developing complications such as urinary tract infections, but protect against other complications such as urine leakage or narrowing of the ureter. The best time for the removal of the stent is, therefore, not known. Here, we want to find out if removing the stent 6-8 days post kidney transplant (i.e. before discharge from hospital) will reduce the number of urinary tract infections and urological complications and also reduce the number of admissions to hospital compared to the current practice.

Who can participate?
Patients who have had a recent single kidney transplant and a ureteric stent inserted.

What does the study involve?
To find out which treatment is best, participants are randomly allocated into one of two groups. Those in group 1 have their stent removed 6-8 days after their transplant. Those in group 2 have their stent removed 4-6 weeks after their transplant. Both the participant and the researchers know which group the participant has been placed in. Each participant is followed up according to the normal standard of care post kidney transplant. They do not have to make any more visits to clinic than any other patient who receives a kidney transplant. All kidney transplant patients are required to provide a mid-stream urine sample when they attend the clinic. A member of the research team monitors and records each participant's urine results and their progress for 3 months following their surgery. An ultrasound of the transplanted kidney is performed at 3 months as part of the study to look for any abnormalities.

What are the possible benefits and risks of participating?
The study might not benefit the participants directly, but the information from the study will

help improve the treatment for future kidney transplant patients. We do not foresee any possible disadvantages or risks of taking part in the study as the insertion of the stent is a standard part of kidney transplant surgery.

Where is the study run from?
Addenbrooke’s Hospital (UK).

When is the study starting and how long is it expected to run for?
November 2014 to November 2017.

Who is funding the study?
Addenbrooke's Hospital (UK).

Who is the main contact?
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Contact information

Type(s)
Scientific

Contact name
Mr Kourosh Saeb-Parsy

Contact details
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
v6.1

Study information

Scientific Title

A single centre, open label, randomised controlled study to compare the incidence of urinary tract infections and urological complications among renal transplant recipients who have a ureteric stent removed 6-8 days versus 4-6 weeks post renal transplantation

Acronym
N/A

Study objectives
To reduce the incidence of UTIs post renal transplantations by 40% in the first three months post transplantation, without adversely affecting the incidence of urological complications (urine leak and ureteric stenosis).

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee East of England - Norfolk REC, 16/08/2012, ref.12/EE/0112

Study design
Open-label randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Pre and post transplant information sheet, given to patients

Health condition(s) or problem(s) studied
Urological complications following renal transplantation

Interventions
Group A - Removal of ureteric stent on day 6-8 post renal transplantation
Group B - Removal of ureteric stent during week 4-6 post renal transplantation

Intervention Type
Procedure/Surgery

Primary outcome measure
Composite of incidence of UTI and ureteric complications (urine leaks or ureteric stenosis)

Secondary outcome measures
1. Incidence of UTIs (symptomatic and asymptomatic bacteriuria considered separately)
2. Incidence of urine leak
3. Incidence of ureteric stenosis
4. Patient death
5. Graft loss
6. Surgical complications (renal vein thrombosis, renal artery thrombosis, bleeding, lymphocoele, wound infection, re-operation, urinary retention)
7. Immunological complications (delayed graft function, rejection)
8. Re-admission and duration of inpatient stay
9. Medical complications (myocardial infarction, deep vein thrombosis, pulmonary embolism, new onset diabetes after transplantation [NODAT])

All outcomes (primary and secondary) will be measured at 3 months post transplantation. The outcomes include rates of complications (e.g., urine leak, ureteric stenosis and urinary tract infections). All data will be obtained from a prospectively maintained database and the diagnosis of these complications will be based on standard clinical criteria.

Overall study start date
01/11/2014

Completion date
01/11/2017

Eligibility

Key inclusion criteria
1. Subjects freely giving their consent
2. Adult recipients of a kidney transplant from a living donor or a deceased donor (donation after brain death [DBD] or donation after circulatory death [DCD])

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
Power of study set at 80% at the 0.05 level. A 40% reduction in UTI rate will require a sample size of 332. Sample size therefore set at 350.

Key exclusion criteria
1. Multi-organ transplant recipients such as heart-kidney, liver-kidney and small bowel-kidney transplants (but not simultaneous pancreas-kidney [SPK] transplants).
2. Renal transplant recipients in whom the donor ureter is not anastomosed to the recipient

bladder (e.g., anastomosed onto the native ureter or an ileal conduit)
3. Recipients of double kidney transplants
4. Recipients of kidneys with two ureters

Date of first enrolment
01/11/2014

Date of final enrolment
01/11/2017

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Addenbrooke's Hospital
Cambridge
United Kingdom
CB2 2QQ

Sponsor information

Organisation
Cambridge University Hospitals NHS Foundation Trust and the University of Cambridge (UK)

Sponsor details
Dept of Surgery, Level 9
Box 202
Hills Road
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CB2 2QQ

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/04v54gj93

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Addenbrooke's Hospital (UK)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration