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Ureteric stent in kidney transplantation

Submission date	Recruitment status	[_] Prospectively registered
01/04/2015	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
02/04/2015	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
19/02/2020	Urological and Genital Diseases	[_] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Clare Griffin

Contact details
Manchester Royal Infirmary
Oxford Road
Manchester
United Kingdom
M13 9WL

Additional identifiers

Protocol serial number
8577

Study information

Scientific Title
Umbilical vein catheter versus double J stent in renal transplantation

Study objectives
The current unit policy is to insert D-J stents in all the renal transplant recipients. It is then removed after 6-8 weeks in operating theatre under local anaesthetic with a Flexible Cystoscope.

The aim of this study is to evaluate:
1. Increase or decrease in urological complications compared to D-J stents with particular reference to urinary tract infections, urinary leaks and obstruction.
2. The overall effective cost difference between both procedures

Ethics approval required
Old ethics approval format

Ethics approval(s)
08/H1002/39; First MREC approval date 05/08/2008

Study design
Randomised; Interventional; Design type: Not specified, Treatment

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Topic: Renal disorders; Subtopic: Renal disorders; Disease: All Renal disorders

Interventions
Comparison of D-J Stents

Intervention Type
Device

Primary outcome(s)
1. Complications and cost
2. Increase or decrease in urological complications compared to D-J stents with particular reference

Key secondary outcome(s))
N/A

Completion date
31/03/2014

Eligibility

Key inclusion criteria
1. Adult patients, aged 18 years or over receiving renal transplant from deceased or live donor
2. First or retransplants
3. Patient should be able to give an informed consent
4. Lower Age Limit 18 years

Participant type(s)

Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
300

Key exclusion criteria
1. Ureteric damage at retrieval
2. Skeletonised ureter with doubtful blood supply
3. Thickened contracted bladder
4. Technical difficulties during surgery
5. Repeat reimplantation after leaks and fistulas
6. Simultaneous Kidney and Pancreas Transplant
7. Patient with a body mass index of greater than 32 (or whose body shape, in the opinion of the operating surgeon, is not suitable for the umbilical vein catheter)
8. Patients who have been anuric for longer than three years

Date of first enrolment
01/11/2008

Date of final enrolment
31/03/2014

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Manchester Royal Infirmary
Oxford Road
Manchester
United Kingdom
M13 9WL

Sponsor information

Organisation
Central Manchester & Manchester Childrens University Hospital NHS Trust

ROR
https://ror.org/00he80998

Funder(s)

Funder type
Government

Funder Name
Astellas Pharma Europe

Alternative Name(s)
Astellas Pharma Europe Ltd

Funding Body Type
Private sector organisation

Funding Body Subtype
International organizations

Location
United Kingdom

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?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes