

Ureteric stent in kidney transplantation

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

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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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

Primary study design

Interventional

Study design

Randomised; Interventional; Design type: Not specified, Treatment

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