

# Ureteric stent in kidney transplantation

<b>Submission date</b> 01/04/2015	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 02/04/2015	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 19/02/2020	<b>Condition category</b> Urological and Genital Diseases	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

## **Secondary study design**

Randomised controlled trial

## **Study setting(s)**

Hospital

## **Study type(s)**

Treatment

## **Participant information sheet**

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

## **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 measure**

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

## **Secondary outcome measures**

N/A

**Overall study start date**

01/11/2008

**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

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Both

**Target number of participants**

Planned Sample Size: 300; UK Sample Size: 300

**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**

England

United Kingdom

**Study participating centre**

**Manchester Royal Infirmary**

Oxford Road

Manchester

United Kingdom

M13 9WL

## **Sponsor information**

**Organisation**

Central Manchester & Manchester Childrens University Hospital NHS Trust

**Sponsor details**

Department of Gastroenterology

Manchester Royal Infirmary

Oxford Road

Manchester

England

United Kingdom

M13 9PL

**Sponsor type**

Hospital/treatment centre

**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**

**Publication and dissemination plan**

Not provided at time of registration

2015 results presented at the American Transplant Congress in <https://atcmeetingabstracts.com/abstract/umbilical-vein-catheter-versus-double-j-stent-for-ureteric-anastomosis-in-renal-transplantation-a-single-centre-open-label-randomized-trial/> (added 19/02/2020)

**Intention to publish date**

**Individual participant data (IPD) sharing plan**

**IPD sharing plan summary**

Not provided at time of registration