No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

Source

NTR

Brief title

DUET Trial

Health condition

Urological complications in kidney transplant recipients.

Sponsors and support

Primary sponsor :	Erasmus MC, University Medical Center Rotterdam, Dept. of Surgery, Group of Hepatopancreatobiliary and Transplant Surgery
Source(s) of monetary or material Support :	Erasmus MC

Intervention

Outcome measures

Primary outcome

To assess whether Double J stenting is superior to externalized single J stenting in preventing urological complications after kidney transplantation.

Secondary outcome

To assess which kind of stent is superior in reducing the total amount of urological complications, radiological interventions, surgical interventions, haematuria, and urinary tract infections. Stent obstructions or dysfunctions will be scored. Additionally, a quality of life and cost effectiveness analysis will be performed with questionnaires. Validated questionnaires for pain, quality of life, health state, work efforts and disabilities in daily life are measured by VAS, Euro-Qol, SF-36 and 'Werk en Zorg'. All questionnaires will be filled in pre-operatively and post-operatively at different time points.

Study description

Study objective

Kidney transplantation is the only treatment offering long-term benefit to patients with chronic kidney failure. Urological complications after kidney transplantation, such as urinary leakage and ureteral strictures, are associated with significant morbidity, surgical and radiological interventions, prolonged hospital stay and even mortality. The majority of urological complications are related to the ureteroneocystostomy and a first sign is often placement of a percutaneous nephrostomy (PCN) drain. It has been demonstrated that stent placement can minimize the number of urological complications. Two types of ureteral stents can be used; an internalized double J stent en an externalized single J stent. In our center, we have used an external stent for several years and urological complications are reported up to 9% of the kidney transplant recipients. However, in literature the double J stent even has less urological complications. Unfortunately, all these studies have a retrospective design and no prospective randomized controlled trials are available. Therefore, in the DUET-trial we will investigate whether double J stenting is indeed superior to the use of an external stent in reducing the number of urological complications after kidney transplantation, as measured by the number of PCN placements.

Study design

Primary endpoint: The primary endpoint will be measured as placement of a PCN within six months after kidney transplantation.

Secondary endpoints:

Information on the occurrence of urinary tract infection, hematuria, radiological interventions

as well as surgical interventions will be collected via the medical record of the recipient.

recipients will be asked to fill in the questionnaires pre-operatively and at two weeks, six weeks and six months post-operatively.

Intervention

Participants who are randomized to external stenting (control group, current standard care in our center) will receive an externalised 7 French ureteric stent. Participants who are randomized to double J stenting will receive a short (12cm) internal Double J 7 French stent. The tip of both stents will be positioned in the pelvis of the transplanted kidney. External stents will be removed 9 days post-operatively. Double J stents will be removed after 3 weeks by cystoscopy in the outpatient clinic of the department of urology. An antibiotic prophylaxis will be used during this procedure based on the latest urinary cultures.

Furthermore, all participants will be asked to fill in questionnaires at different time points, including a Visual Analogue Score (VAS), quality of life questionnaire (SF-36), Euro-Qol (EQ-5D) and “Werk en Zorg” questionnaires

Contacts

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Eligibility criteria

Inclusion criteria

All adult kidney transplant recipients in the Erasmus University Medical Center (>18yrs) are invited to participate

Exclusion criteria

1. Patients with a reconstructed urinary tract or conduit after total or partial cystectomy.

2. Patients with bladder dysfunction that requires continuous or intermittent catheterization.

3. Patients who do not understand the Dutch language sufficiently to sign the informed consent forms and to fill in the questionnaires

4. Donor kidneys with more than one ureter

5. Patients with primary FSGS and residual urine production. Because FSGS is known for its quick recurrence in the kidney graft and the first sign is proteinuria. With an externalized stent we are able to distinguish between proteinuria of the transplant kidney and the native kidneys.

Study design

Design

Study type :	Interventional
Intervention model :	Parallel
Allocation :	Randomized controlled trial
Masking :	Open (masking not used)
Control :	N/A , unknown

Recruitment

NL

Recruitment status :	Pending
Start date (anticipated) :	01-08-2018
Enrollment :	300
Type :	Anticipated

Ethics review

Positive opinion

Date :	19-07-2018

Application type : First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL7183
NTR-old	NTR7374
Other	: MEC-2016-678

Study results

Summary results

not yet, study is ongoing