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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...

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

Bron

NTR

Verkorte titel

DUET Trial

Aandoening

Urological complications in kidney transplant recipients.

Ondersteuning

Primaire sponsor :	Erasmus MC, University Medical Center Rotterdam, Dept. of Surgery, Group of Hepatopancreatobiliary and Transplant Surgery
Overige ondersteuning :	Erasmus MC

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Doel van het onderzoek

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.

Onderzoeksopzet

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.

Onderzoeksproduct en/of interventie

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

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type :	Interventie onderzoek
Onderzoeksmodel :	Parallel
Toewijzing :	Gerandomiseerd
Blinding :	Open / niet geblindeerd
Controle :	N.v.t. / onbekend

Deelname

Nederland	
Status :	Werving nog niet gestart
(Verwachte) startdatum :	01-08-2018
Aantal proefpersonen :	300
Type :	Verwachte startdatum

Ethische beoordeling

Positief advies	
Datum :	19-07-2018
Soort :	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten

Samenvatting resultaten

not yet, study is ongoing