DUET-trial; DoUble j or External stenting during kidney Transplantation? Study-protocol

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Urinary tract signs and symptoms
Study type	Interventional

Summary

ID

NL-OMON47037

Source
ToetsingOnline

Brief title
DUET-trial

Condition

- Urinary tract signs and symptoms
- Renal and urinary tract therapeutic procedures

Synonym
Urological complications after kidney transplantatie

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Kidney, Stent, Transplant, Urological

Outcome measures

Primary outcome

Our main study endpoint is the number of percutaneous nephrostomy (PCN) drainages.

Secondary outcome

The secondary study parameters are the number of urinary tract infections, macroscopic haematuria, radiological interventions, surgical re-interventions and stent obstruction or dysfunction. Additionally, a quality of life and cost effectiveness analysis will be performed by using questionnaires. Validated questionnaires for pain, quality of life, health state, work efforts and disabilities in daily life are measured by the VAS, Euro-Qol, SF-36 and *Werk en Zorg*.

Study description

Background summary

Urological complications after kidney transplantation, such as urinary leakage and ureteral strictures, are associated with significant morbidity, surgical or radiological re-interventions, prolonged hospital stay and even mortality. The majority of urological complications are related to the ureteroneocystostomy. Stent placement can minimize the number of urological complications. Two types of ureteral stents can be used; mainly divided in internal double J stents and external single J stents. 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 several studies even report less urological complications using a double J stent (0-5,4%). Unfortunately, all these studies have a retrospective design and no prospective randomized

controlled trials are available.

Study objective

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

This will be a single-centre randomized controlled trial with a superiority design. Since patients and physicians will notice post-operatively the presence of an external stent, the study cannot be blinded. Participants will be included during a period of 3 years, 100 recipients each year. Last follow-up moment of all questionnaires will 6 months after transplantation.

Intervention

Randomization between double J and external stenting.

In the group which randomized to double-J stents, an additional cystoscopy will be required in order to remove the stent. Furthermore, both groups are asked to fill in questionnaires at 4 different time points.

Study burden and risks

Participants will be need 15min to finish 1 questionnaire. (4X15min= 60min in total)
In addition, the patients who randomized to the double-J stent must undergo a cystoscopy to remove the stent after 3 weeks. This intervention will be conducted at the outpatient clinic of the department of urology. This is done under local anesthesia, with an antibiotic prophylaxis. Patients may leave the hospital after about 30min.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

All adult kidney transplant recipients that will be transplanted at the Erasmus University Medical Center (>18yrs) are invited to participate.

Exclusion criteria

Patients will be excluded if they do not understand the Dutch language sufficiently to sign the informed consent forms and to fill in the questionnaires, or if they have a reconstructed urinary tract or conduit after total or partial cystectomy, a bladder dysfunction that requires continuous or intermittent catheterization, or will receive a donor kidney with more than one ureter. In addition, patients with primary FSGS and residual urine production will be excluded.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel

Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	12-12-2018
Enrollment:	300
Type:	Actual

Medical products/devices used

Generic name:	Double J stent Ch7 12cm
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	09-03-2017
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	16-05-2018
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	19-11-2018
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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
CCMO	NL59551.078.16