Prevention of urological complications in living kidney transplantation: stenting or not?

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Primary objective: To asses if stenting of the ureteroneocystostomy in living kidney transplantation recipients is necessary to prevent urological complications.Secondary objective: To assess if stenting influences the total amount of urological...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON41447

Source
ToetsingOnline

Brief title
SPLINT-trial

Condition

- Other condition

Synonym
kidney transplantation, urological complications

Health condition

nier 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: living donor kidney transplantation, stenting, urological complications

Outcome measures

Primary outcome

Percutaneous Nephrostomy placement

Secondary outcome

Urinary tract infection

Haematuria

Radiological interventions

Surgical re-interventions

Stent obstruction or dysfunction

Additionally, a quality of life and cost effectiveness analysis will be

preformed with questionnaires. Validated questionnaires for quality of life,

health state, work efforts and disabilities in daily life are measured by the

Euro-Qol, SF-36 and *Werk en Zorg*.

Study description

Background summary

Kidney transplantation is the only treatment offering long-term benefit to patients with chronic kidney failure. Urological complications after kidney transplantation are associated with significant morbidity, mortality, prolonged hospital stay and a radiological intervention or second surgical procedure is frequently required. The majority of urological complications are related to

the ureteroneocystostomy and a first sign is often placement of a percutaneous nephrostomy (PCN) drain1. It has been suggested that routine use of a prophylactic ureteral stent (splint) in kidney transplantation may diminish the risk of urological complications. However, the role of ureteral stents in living donor kidney transplantation is not well defined and there is concern about potential stent related complications as infection, obstruction, stent migration, breakage, stone formation, haematuria, and secondary ureter obstruction. Most surgeons make a choice based on their training, and not based on specific rationale or literature. To date, 5 randomized controlled trials2-6 on stent placement have been reported; however, they differ in study design concerning living or deceased donation, type of ureteroneocystostomy anastomosis (intravesical or extravesical), type of stent and donor or recipient characteristics. An advantage for stent placement is suggested, but notably, in some studies on routine basis and in others on strictly defined criteria. A meta-analysis7 on this topic supports the use of ureteral stents in selected recipients, but without a statement on routine stenting, type of stent and timing of stent removal8. In this study the hypothesis will be tested if omitting a stent is at least as effective as the use of a stent or even reduces urological complications, stent related complications, and PCN placements in kidney transplantation.

Study objective

Primary objective: To asses if stenting of the ureteroneocystostomy in living kidney transplantation recipients is necessary to prevent urological complications.

Secondary objective: To assess if stenting influences 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 preformed with questionnaires. Validated questionnaires for quality of life, health state, work efforts and disabilities in daily life are measured by the Euro-Qol, SF-36 and *Werk en Zorg*. All questionnaires will be filled in pre-operatively and post-operatively at different time points.

Study design

This will be a single-centre randomized controlled trial with a non-inferiority design. Randomization will be performed after intubation in the operation room by a envelop randomization system. All inclusions will be performed in 2 years, 100 recipients each year. Last follow-up moment of all questionnaires will be after one year.

Intervention

Nowadays, our clinical practice is the use of a stent in case of kidney transplantations from a living kidney donation. Our *intervention* will be the non-use of a stent. Alongside, we will ask the recipients to fill in a questionnaire to analyse the quality of life and make a cost-effectiveness analysis.

Study burden and risks

There is no additional risk for the patient or the operation. Patients in one or the other group may have benefit, but only with this randomized controlled trial we can identify the beneficial operation. As literature is inconclusive according to stent use, we do not know the benefits.

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

Participants who will receive a living donor kidney transplantation and speak the Dutch language sufficiently to sign the informed consent forms and to fill in the questionnaires.

Exclusion criteria

- Patients with a reconstructed urinary tract or conduit after total or partial cystectomy.
- Patients with bladder dysfunction that requires continuous or intermittent catheterization.
- Age <18 years
- Donor kidneys with more than one ureter

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:	Recruiting
Start date (anticipated):	08-04-2014
Enrollment:	200
Type:	Actual

Ethics review

Approved WMO

Date:	22-01-2014
Application type:	First submission

Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	17-06-2015
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	NL44423.078.13