Urological complications after live donor kidney transplantation: intravesical or extravesical ureterovesical anastomosis?

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Main objective: Does the use of the extravesical ureterovesicostomy reduce the incidence of PCN placement, and urological complications?Secondary objective: Does the use of the extravesical ureterovesicostomy reduces the rate of re-operations and re...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Renal disorders (excl nephropathies)
Study type	Interventional

Summary

ID

NL-OMON35307

Source
ToetsingOnline

Brief title
INEX-trial

Condition

- Renal disorders (excl nephropathies)

Synonym
kidney transplantation from living donor

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: extravesical., intravesical, living donor kidney transplantation, Ureterovesicostomy

Outcome measures

Primary outcome

Main study parameter/endpoint

A change from 22% to 7% PCN placement by use of the extravesical

ureterovesicostomy.

Secondary outcome

Secondary study parameters/endpoints

Does the use of the extravesical ureterovesicostomy reduces the rate of

re-operations and re-interventions for urological complications, and reduces

operation time and costs.

Other study parameters

Other study parameters are baseline values, which might intervene with the main

study parameter: age, recipient, donor age gender, BMI, smoking, ASA

classification, side of the procured kidney, number of renal arteries and

number of renal veins.

Study description

Background summary

Urological complications after renal transplantation cause significant patient morbidity and may result in transplant failure. The risk of urological complications after kidney transplantation is as high as 2.5% up to 30%. The majority of urological complications is related to the ureterovesical anastomosis and occurs within 3 months after transplantation.

Successful formation of the ureterovesical anastomosis is important in preventing complications and securing a functional transplant. Several techniques for ureterovesical anastomosis are described, with variable outcome. The surgical protocol for transplant ureteroneocystostomy has oscillated between intravesical and extravesical procedures. No technique has been convincingly proven to be superior to the other, although some studies suggest the superiority of the extra-vesical technique; the extravesical technique requires a shorter length of ureter, which may decrease the risk of distal ureteric ischemia, and a separate cystotomy is not required. In our center the standard technique is the intra-vesical technique with placement of a supra pubic stent in the pyelum of the donor kidney. Approximately 22% of the recipients of a live kidney donation receive a percutaneous nephrostomy catheter (PCN) for urological complications. PCN can be seen as a measure for the urological complications.
The aim of this study is to assess the rate of percutaneous nephrostomy (PCN) placement for urological complications in patients with an intra and extravesical ureterovesical anastomosis in live kidney transplantation. We hypothesize that extravesical technique reduces the incidence of PCN placement, and urological complications.

Study objective

Main objective: Does the use of the extravesical ureterovesicostomy reduce the incidence of PCN placement, and urological complications?
Secondary objective: Does the use of the extravesical ureterovesicostomy reduces the rate of re-operations and re-interventions for urological complications, and reduces operation time and costs.

Study design

Dubbel blind randomized controlled trial.

Intervention

Intravesical ureterovesicostomy was performed after graft vascularization via an anterior cystotomy to visualize the interior of the bladder. Briefly, this consisted of a small anterior cystostomy and the spatulated lower ureter was anastomosed to the bladder mucosa with interrupted sutures.
Extravesical ureterovesicostomy was performed after graft vascularization. The donor ureter length was modified to avoid redundancy and was usually shorter than that needed for an intravesical approach. A myotomy was made with cautery on the anterolateral surface of the bladder. This incision was continued through the seromuscular layer until mucosa bulged through. The ureter was trimmed and the full thickness of the ureter was anastomosed to the bladder mucosa beginning with two-quadrant interrupted sutures. The sutures were used to complete the anastomosis in a running fashion between each quadrant stay

suture, creating a water-tight closure. During both techniques a supra pubic stent is placed in the donor pyelym. In addition three kidney biopsies are taken in each patient and send to the pathologist until further analysis for possible ischemia, inflammation etc.

Study burden and risks

The burden and risks associated with participation is limited to one of the two surgical techniques of ureterovesicostomy and to the perioperative kidney biopsies. The amount and number of blood samples, the number of site visits and physical examinations is the same as in a standard work-up of a kidney transplant recipient.

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

Inclusion criteria: All kidney transplant recipients from a living donor, who are medically able to receive a kidney, can participate. Recipients must be older than 18 years.

Exclusion criteria

Exclusion criteria: Donorkidneys with more than one ureter and recipients younger than 18 years.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	20-10-2010
Enrollment:	200
Type:	Actual

Ethics review

Approved WMO

Date:	11-02-2010
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Approved WMO Date:	20-07-2010
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	27-01-2011
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	NL29527.078.09