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

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON20938

Source
NTR

Brief title
INEX-trial

Health condition

renal transplant, live kidney donors, renal failure

Sponsors and support

Primary sponsor: sponsor Erasmus Medical Center
address P.O. Box 2040
postal code 3000 CA
city Rotterdam
country The Netherlands
phone +31 (0)10 4639222
Source(s) of monetary or material Support: Mrace Comittee, Erasmus MC

Intervention

Outcome measures

Primary outcome

Number of PCN placements by use of the extravesical ureterovesicostomy.

Secondary outcome

1. Number of re-operations and re-interventions for urological complications;

2. Operation time;

3. Costs.

Study description

Background summary

Urological complications after renal transplantation cause significant patient morbidity and may result in transplant failure. 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 extravesical technique. In our center the standard technique is the intravesical technique. In case an urological complication (e.g. ureteral stenosis) occurs after transplantation, we might decide to place a percutaneous nephrostomy catheter (PCN). PCN can therefore been 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, in order to determine which anastomosis technique has the least urological complications.

Study objective

Our hypothesis is that the extravesical technique reduces the incidence of PCN placement, and urological complications.

Study design

Follow-up will be 1 year.

Intervention

1. Intervention: Extravesical ureterovesical anastomosis technique;

2. Control: Intravesical ureterovesical anastomosis technique.

Contacts

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Eligibility criteria

Inclusion criteria

All kidney transplant recipients from a living donor, who are medically able to receive a kidney, can participate.

Exclusion criteria

1. Recipients younger than 18 years;

2. Donor kidneys with more than one ureter.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-06-2010
Enrollment:	200
Type:	Actual

Ethics review

Positive opinion

Date:	10-05-2010
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	NL2196
NTR-old	NTR2320
Other	METC Erasmus MC : MEC-2009-385
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A