Splint-tial: Stent PLacement IN living kidney Transplantation

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON25009

Source
NTR

Brief title
Splint-trial

Health condition

renal transplant, live kidney donors, stent

Sponsors and support

Primary sponsor: Prof. dr. J.N.M. IJzermans
Source(s) of monetary or material Support: -

Intervention

Outcome measures

Primary outcome

Number of PCN placements

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’.
Other study parameters are baseline values, which might intervene with the main study parameter: donor age and gender, recipient age and gender, body mass index, smoking, ASA classification, operation time and return to normal daily activities.

Study description

Background summary

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) drain. 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.The aim of this study is to assess the rate of urological complications in patients with and without stent placement in live kidney transplantation.

Study objective

Our hypothesis is that a reduction of urological complications in living kidney transplantation can be achieved without stent placement

Study design

Follow-up will be 1 year

Intervention

1. Intervention: No stent placement
2. Control: Stent placement

Contacts

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Eligibility criteria

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-03-2014
Enrollment:	200
Type:	Anticipated

Ethics review

Positive opinion

Date:	09-04-2014
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	NL4358
NTR-old	NTR4498
Other	METC Erasmus MC : MEC-2013-196

Study results