Splint-tial: Stent PLacement IN living kidney Transplantation

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

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON25009

Bron
NTR

Verkorte titel
Splint-trial

Aandoening

renal transplant, live kidney donors, stent

Ondersteuning

Primaire sponsor: Prof. dr. J.N.M. IJzermans
Overige ondersteuning: -

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Number of PCN placements

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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

Onderzoeksopzet

Follow-up will be 1 year

Onderzoeksproduct en/of interventie

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

Contactpersonen

Publiek

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The Netherlands

Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- 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

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-03-2014
Aantal proefpersonen:	200
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	09-04-2014
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL4358
NTR-old	NTR4498
Ander register	METC Erasmus MC : MEC-2013-196

Resultaten