Prolonged ex-vivo normothermic machine perfusion for kidney regeneration

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Prolonged normothermic machine perfusion (PNMP) can be used to ex-vivo regenerate marginal donor organs, resulting in increased kidney graft viability and survival of the transplanted organ.

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

Samenvatting

ID

NL-OMON26491

Bron
Nationaal Trial Register

Verkorte titel
PROPER

Aandoening

Patients with end-stage renal disease undergoing a kidney transplantation

Ondersteuning

Primaire sponsor: Leiden University Medical Center
Overige ondersteuning: Nierstichting

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The primary clinical outcome will be the glomerular filtration rate (GFR) at 6 months post transplantation.

Toelichting onderzoek

Achtergrond van het onderzoek

Chronic kidney disease is a debilitating condition with a poor quality of life. Dialysis offers little improvement in this medical condition which carries a mortality rate that surpasses most cancers. Dialysis is one of the most expensive treatments, putting pressure on the sustainability of the health care system. Currently kidney transplantation is the only viable option for patients with kidney failure to regain quality of life and health. The number of organs available for transplantation is insufficient with a widening gap between supply and demand. Nowadays, centers accept older and higher risk donor organs with co-morbidity, often leading to non-function, complications and with half of the patients back on dialysis within 15 years. Furthermore, many donor kidneys have to be discarded as too damaged and beyond repair. Increasing the quality and therefore transplantability of these high-risk donor organs could significantly increase the donor kidney pool.
We would like to introduce and clinically evaluate prolonged normothermic machine perfusion (PNMP) to challenge this situation. Using prolonged normothermic perfusion of marginal donor organs, we aim to kick
start regeneration in the kidney before transplantation, improving function and survival long-term. Furthermore, the choice to accept or decline a donor kidney organ is currently based on subjective criteria and causes great uncertainty amongst clinicians. There is a dire need for tools to aid in decision making and reduce this uncertainty. Biomarkers predictive of graft regeneration are lacking. Samples from perfused kidneys and donor recipients will be collected and analysed to allow the formulation of a kidney fitness index.

Doel van het onderzoek

Prolonged normothermic machine perfusion (PNMP) can be used to ex-vivo regenerate marginal donor organs, resulting in increased kidney graft viability and survival of the transplanted organ.

Onderzoeksopzet

1 year

Onderzoeksproduct en/of interventie

Eligible and consenting patients who will receive a donor kidney will be included for participation in this study. Current practice is to preserve donor kidneys on hypothermic machine perfusion (HMP). In this study, donor kidneys (n=18) will be taken off the HMP after arrival in the transplant center. These will then be perfused with oxygenated perfusate using the NMP device following an optimised NMP protocol. First, a cohort of DCD kidneys (n=6) will be subjected to 1 hour of NMP and subsequently transplanted [NMP1]. Before extending the duration, secondary endpoints will be evaluated. Thereafter, the duration of NMP will be prolonged to 3 hours (n=6) [PNMP3] and consequently 6 hours (n=6) [PNMP6].

Contactpersonen

Publiek

Leiden University Medical Center
Asel Arykbaeva

0657316416

Wetenschappelijk

Leiden University Medical Center
Asel Arykbaeva

0657316416

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

• Patients undergoing 1st or 2nd kidney transplant
• Patients undergoing a kidney transplantation from DCD Maastricht III & V
• Transplant recipients aged ≥ 18 years
• Written informed consent

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

• Patients undergoing 3rd or subsequent kidney transplant
• Patients undergoing a kidney transplantation from DCD Maastricht I, II & IV
• Transplant recipients aged < 18 years
• Patients receiving multi-organ transplants
• ABO/HLA incompatible transplants
• Highly sensitized patients with a panel-reactive antibody (PRA) ≥85%
• Kidneys with CIT > 12 hrs at the point of arrival at transplant centre
• Kidneys with complex vascular anatomy (≥3 arteries, artery which cannot be can-nulated or attached to the patch holder)
• Kidneys explanted from a donor on normothermic regional perfusion

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-12-2021
Aantal proefpersonen:	18
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nee

Ethische beoordeling

Positief advies

Datum:	09-03-2020
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 52366
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL8446
CCMO	NL76344.058.20
OMON	NL-OMON52366

Resultaten