Prolonged ex-vivo normothermic machine perfusion for kidney regeneration

No registrations found.

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

Summary

ID

NL-OMON26491

Source
NTR

Brief title
PROPER

Health condition

Patients with end-stage renal disease undergoing a kidney transplantation

Sponsors and support

Primary sponsor: Leiden University Medical Center
Source(s) of monetary or material Support: Nierstichting

Intervention

Outcome measures

Primary outcome

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

Secondary outcome

Secondary clinical endpoints will include primary non-function, delayed graft function (DGF), patient and graft survival, 7 days and 3 month estimated glomerular filtration rate (eGFR-CKD EPI formula), adverse events and organ discards. Biopsies, samples of perfusate, blood and urine will be collected for biomarker analysis.

Study description

Background summary

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.

Study objective

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.

Study design

1 year

Intervention

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].

Contacts

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Eligibility criteria

Inclusion criteria

• 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

Exclusion criteria

• 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

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-12-2021
Enrollment:	18
Type:	Anticipated

IPD sharing statement

Plan to share IPD: No

Ethics review

Positive opinion

Date:	09-03-2020
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 52366
Bron: ToetsingOnline

Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

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

Study results