The applicability of machine perfusion preservation by the Airdrive system in kidney transplantation.

No registrations found.

Ethical review	Not applicable
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON22914

Source
NTR

Health condition

The patiënts which are to be included in this study have kidney problems which can only be treated by kidney replacement therapy In this pilot we do not study the underlying disease We study the safety of a new machine perfusion system

Sponsors and support

Primary sponsor: Academic Medical Center Amsterdam
Meibergdreef 9
1105 AZ
Amsterdam
Source(s) of monetary or material Support: AMC Medical Research
Meibergdreef 9
1105 AZ
Amsterdam

Intervention

Outcome measures

Primary outcome

The absence of adverse events due to the use of Airdrive oxygenated machine perfusion as preservation method during kidney transplantation.

Secondary outcome

Renal function parameters such as serum creatinine and blood urea will be evaluated, as well as histological analyses of a perioperatively harvested graft biopsy.

Study description

Background summary

Kidney donor graft shortage for transplantation has led to the use of marginal donors such as non-heart beating donor (NHBD) kidneys. As perfusion in this category of donor patients is absent prior to graft nephrectomy, NHBD kidneys suffer warm ischemia, causing damage, which is associated with early and late graft loss. Preservation of the graft by hypothermic machine perfusion instead of conventional cold static storage provides a viable solution to reduce the warm ischemic damage-induced graft loss. In preclinical animal studies, the Airdrive™ machine perfusion system has shown to be safe, and to improve renal function and graft structural integrity after induced warm ischemic damage. The next step is to introduce the Airdrive™ system in a clinical setting. To this end, a pilot-study using the Airdrive™ system for the preservation of kidney grafts was devised to demonstrate that the machine perfusion system is ‘safe’ for use in the clinical setting. In this pilot-study we hypothesize that the use of the Airdrive™ machine perfusion system is safe and technically feasible for graft preservation in kidney transplantation.

Study objective

It is safe to use the Airdrive machine perfusion system as a preservation method in kidney transplantation.

Study design

Renal function parameters will be routinely checked and are all part of the standard patient care protocol of the AMC hospital.

Intervention

All seven kidney grafts will be preserved using the Airdrive machine perfusion system

between arrival at the AMC and implantation in the recipient instead of continuation of conventional cold storage.

Contacts

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Eligibility criteria

Inclusion criteria

- Patient has to be at least 18 years of age and mentally competent;

- Voluntary signed and dated Informed Consent Form of the patient has to be obtained prior to any study-specific procedure.

Exclusion criteria

Kidney grafts which are expected to be transplanted within 2 hours after arrival in the AMC,

will be excluded to guarantee no extension of cold ischemic times due to Airdrive™ machine perfusion. Estimation of this duration will be done by the transplant surgeon or surgical resident.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	04-05-2016
Enrollment:	7
Type:	Anticipated

Ethics review

Not applicable

Application type:	Not applicable

Study registrations

Followed up by the following (possibly more current) registration

ID: 42777
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL5695
NTR-old	NTR5847
CCMO	NL52704.018.15
OMON	NL-OMON42777

Study results

Summary results
Doorschodt B.M., et al., Evaluation of a novel system for hypothermic oxygenated pulsatile perfusion preservation. Int J of Artif Organs 32, 728-38 2009
Schreinemachers M.C. et al., Pulsatile perfusion of warm ischaemia damaged experimental kidney grafts. Br. J of Surg 97, 349-358 2010