The use of the Airdrive* machine perfusion system in graft preservation during kidney transplantation: a pilot study in kidney transplantation of grafts from post-mortem donors.

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The objective is to assess the safety profile of the hypothermic Airdrive* oxygenated machine perfusion system for graft preservation in kidney transplantation.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Renal and urinary tract therapeutic procedures
Study type	Observational non invasive

Summary

ID

NL-OMON42777

Source
ToetsingOnline

Brief title
Airdrive*

Condition

- Renal and urinary tract therapeutic procedures

Synonym
Kidney transplantation for kidney failure

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: AMC foundation,Oxiplenish

Intervention

Keyword: Airdrive, Kidney transplantation, Machine perfusion, Organ preservation

Outcome measures

Primary outcome

The main study endpoint is the absence of adverse effects due to the use of Airdrive* machine perfusion as preservation method. Every unexpected event possibly related to the use of the Airdrive* that occurs during the transplantation procedure or within 1-month follow-up, will be evaluated (perioperative cardiovascular incidents, haematological abnormalities, postoperative infections and clinical parameters).

Secondary outcome

Secondary endpoints comprise perfusion parameters, which are recorded as part of the Airdrive* system.

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

The objective is to assess the safety profile of the hypothermic Airdrive* oxygenated machine perfusion system for graft preservation in kidney transplantation.

Study design

In this prospective pilot study recipients of kidney grafts from post-mortem donors are recruited by the transplant surgeon. The recipients will be included after having given informed consent. Before surgery, after arrival and inspection of the cold stored kidney graft in the AMC, the graft will be washed out using Belzer*s University of Wisconsin machine perfusion solution (UW-MPS) . When the graft is completely flushed, hypothermic machine perfusion preservation starts by connecting the renal artery of the graft to the Airdrive* machine perfusion system instead of a continuation of cold static storage. Airdrive* machine preservation ends approximately 3 hours later, just before implantation of the graft in the recipient. In case of failure of the pump system, preservation of the graft falls back to static cold storage as the cold environment is maintained until transplantation. Except for the use of machine perfusion, the entire transplantation procedure as well as the investigational follow-up will comply with standard clinical practice for kidney transplantation of grafts from post-mortem donors (including blood and urine sampling). During the machine perfusion and transplantation procedure, possible side effects which may be attributable the use of the Airdrive* are monitored and recorded. During the transplant procedure and shortly thereafter, vital parameters (among others, pulse and blood pressure) will be monitored to assess possible adverse effects of the use of Airdrive* machine preservation. Also, after the transplantation procedure has been completed, the recipient will be observed to monitor possible adverse reactions. Postoperative recovery during admission will be evaluated (physical condition, blood sampling, urine sampling). After discharge, follow-up will continue until 1 month after transplantation.

Study burden and risks

The kidney graft recipients require kidney transplantation, according to standard clinical indications. Washout of the graft and hypothermic storage until implantation into the recipient is also part of normal preparations for

transplantation of solid organs. In this study the clinical standard organ preservation method (cold static storage) applied in the time between arrival of the kidney graft and implantation in the recipient, will be replaced by hypothermic Airdrive* machine perfusion preservation of the graft. Additionally, the clinical standard organ preservation solution (i.e., UW-CS) will be replaced with the same type of preservation solution modified for optimal machine perfusion (i.e., UW-MPS).
Although not the purpose of this study, there might be a direct advantage for the kidney recipient, as the function of the graft retrieved from post-mortem nephrectomy may be impaired due to warm ischemic-exposure and/or prolonged cold ischemic times. In these cases, the use of machine perfusion preservation of the graft has shown to be a benefit. Risks other than the usual risks associated with undergoing kidney transplantation of grafts from post-mortem donors, are possible risks related to adverse effects of the use of the Airdrive* system for preservation of the graft prior to transplantation. As side effects that could be attributed to the use of the Airdrive* system have not been encountered in the preclinical trials, possible adverse effects are not anticipated, however need to be confirmed in the clinical setting.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Patients eligble for kidney transplantation from a post-mortem donor, who are at least 18 years of age and mentally competent.

Exclusion criteria

Patient is mentally incompetent and/or has an age of 17 or less.
The time between arrival of the graft in the AMC and the transplantation into the patient is expected to be less than 2 hours, as estimated by the transplant surgeon or surgical resident.

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	06-07-2016
Enrollment:	7
Type:	Actual

Medical products/devices used

Generic name:	Airdrive machine perfusion preservation of kidney graft
Registration:	No

Ethics review

Approved WMO Date:	19-01-2016
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	03-11-2016
Application type:	Amendment
Review commission:	METC Amsterdam UMC

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 22914
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL52704.018.15
OMON	NL-OMON22914