The use of Polysol® as a wash-out and preservation solution in kidney transplantation: a pilot study in living (un)related donors

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Is Polysol® safe for use as a wash-out and preservation solution in kidney transplantation?

Ethical review	Approved WMO
Status	Pending
Health condition type	Renal disorders (excl nephropathies)
Study type	Observational non invasive

Summary

ID

NL-OMON32207

Source
ToetsingOnline

Brief title
Polysafe

Condition

- Renal disorders (excl nephropathies)
- Therapeutic procedures and supportive care NEC

Synonym
renal failure

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W,Doorzand Polysol

B.V.,Spoelvloeistof wordt ter beschikking gesteld door de producent

Intervention

Keyword: donor organ, kidney, preservation, transplantation

Outcome measures

Primary outcome

The absence of adverse reactions due to the use of Polysol® as a wash-out and preservation solution during kidney transplantation. Every unexpected event possibly related to the use of Polysol®, that occurs during the transplantation procedure or within 1 month of follow-up, will be evaluated (peri-operative cardiovascular incidents, hematological abnormalities, post-operative infections and clinical parameters).

Secondary outcome

n.a.

Study description

Background summary

The increasing shortage of donor organs has led to the necessity of expansion of the donor pool. Since current organ preservation methods do not suffice, improvement of preservation methods is essential to increase the amount of donor organs available for transplantation.
Recently, a new improved perfusion preservation solution, Polysol®, and perfusion preservation system named Airdrive® have been developed for hypothermic MP of kidney and liver grafts at the Surgical Laboratory of the Academic Medical Center. Results of pre-clinical tests using Polysol® as a flushing and preservation solution as well as in combination with the Airdrive® show a significantly improved preservation quality of donor grafts, in clinically relevant large animal transplantation models compared with current clinical standards. Adverse reactions of the use of Polysol® have not been encountered in the pre-clinical trials.
Polysol® as well as the Airdrive® perfusion system in combination with Polysol®

can be introduced in a clinical setting if the perfusion preservation solution Polysol® can be considered *safe* for use in the clinical setting. Therefore, a pilot-study using Polysol® for the preservation of kidney grafts is required.

Study objective

Is Polysol® safe for use as a wash-out and preservation solution in kidney transplantation?

Study design

In this prospective pilot study consenting kidney donors and their recipients are recruited by the transplant surgeon. The (living) donors and their recipients will be included when both the donor and the recipient have given their informed consent. The donor will not encounter any additional risks other than the usual risks involved with undergoing surgery. During surgery, after retrieval of the kidney graft, the graft will be washed out of blood remnants using Polysol®, a medical device, as a wash-out solution. Besides the use of a new preservation solution, the entire transplantation procedure as well as the investigational follow-up will be according to standard clinical practice for living (un)related kidney transplantation (including blood and urine sampling). During the wash-out and transplantation procedure, possible side-effects of the use of Polysol® are monitored and recorded. During the revascularization operation and shortly thereafter, vital parameters (a.o. pulse and blood pressure) will be monitored to assess possible adverse reactions of the use of Polysol®. Also, after the transplantation procedure has been completed, the recipient will be observed to monitor possible adverse reactions of the use of Polysol® for wash-out and preservation of the kidney graft. 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 a kidney transplantation, according to standard clinical practice. Wash-out of the graft and hypothermic storage until implantation into the recipient is also part of normal preparations for transplantation of solid organs. As the living (un)related kidney transplantation procedure requires an ex vivo wash-out of blood remnants, the donor will not encounter any additional risks other than the usual risks involved with undergoing surgery. In this study the clinical standard organ preservation solutions for wash-out and preservation of the graft (Viaspan® or Custodiol®) will be replaced by the new solution, Polysol®. There is not a direct advantage for the kidney recipient, as the quality of a donor graft retrieved from a *living donor* (therefore not subjected to a period of warm ischemia) and the time for hypothermic storage both imply an *ideal* graft for

transplantation. Risks other than the usual risks associated with undergoing (living donor) kidney transplantation to which a kidney recipient will be subjected, are risks of the occurrence of adverse reactions of the use of Polysol® for wash-out and preservation of the graft prior to transplantation. As side effects that could be attributed to the use of Polysol® have not been encountered in the pre-clinical trials, possible adverse reactions are not anticipated, however need to be assessed 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

Living (un)related kidney donor-recipient couples over 18 years of age

Exclusion criteria

Kidney donors or recipients in the living (un-)related donor setting under the age of 18 years

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-01-2008
Enrollment:	10
Type:	Anticipated

Medical products/devices used

Generic name:	Perfusion preservation solution for donor organs
Registration:	No

Ethics review

Approved WMO

Application type:	First submission
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

No registrations found.

In other registers

Register	ID
CCMO	NL20493.018.07