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

Gepubliceerd: 04-05-2016 Laatst bijgewerkt: 15-05-2024

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

Ethische beoordeling	Niet van toepassing
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON22914

Bron
NTR

Aandoening

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

Ondersteuning

Primaire sponsor: Academic Medical Center Amsterdam
Meibergdreef 9
1105 AZ
Amsterdam
Overige ondersteuning: AMC Medical Research
Meibergdreef 9
1105 AZ
Amsterdam

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

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.

Contactpersonen

Publiek

Academic Medical Center (AMC), Department of Surgery
P.O. Box 226600
Meibergdreef 9

T.M. Gulik, van
Amsterdam 1100 DD
The Netherlands
Tel +31 20 56 65570

Wetenschappelijk

Academic Medical Center (AMC), Department of Surgery
P.O. Box 226600
Meibergdreef 9

T.M. Gulik, van
Amsterdam 1100 DD
The Netherlands
Tel +31 20 56 65570

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- 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.

Belangrijkste redenen om niet deel te kunnen nemen

(Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

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

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	04-05-2016
Aantal proefpersonen:	7
Type:	Verwachte startdatum

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 42777
Bron: ToetsingOnline

Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten

Samenvatting resultaten
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