A Single Center Clinical Trial to Assess Viability of High Risk Donor Livers using Hypothermic and Normothermic Machine Perfusion with Rewarming Phase Prior to Transplantation

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1.Potentially transplantable high risk donor liver grafts can be distinguished from non-viable high risk donor liver grafts using NMP. 2.DHOPE, prior to ex situ viability assessment, increases the odds of a high risk donor liver graft to be...

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON19890

Bron
NTR

Aandoening

normothermic machine preservation
normothermic machine perfusion
ex-situ viability testing
liver transplantation

normotherme machine preservatie
normtoherme machine perfusie
lever transplantatie

Ondersteuning

Primaire sponsor: R.J. Porte, r.j.porte@umcg.nl, +31503619027 University Medical Center Groningen, Department of Surgery, P.O. Box 30.001, 9700 RB Groningen, the Netherlands

Overige ondersteuning: Sponsor
Tekke Huizenga Foundation

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The feasibility, and reliability of ex-situ viability testing of high risk donor livers using a protocol combining DHOPE, gradual rewarming and NMP, by assessing graft survival at 3 months after transplantation.

Toelichting onderzoek

Achtergrond van het onderzoek

Currently, there is a shortage of suitable donor livers. To expand the donor pool, livers from high risk donors, termed extended criteria donor (ECD) livers are increasingly accepted for transplantation. To counter the increased risk of developing severe complications, such as primary non function (PNF), machine perfusion can be used to evaluate and improve explanted livers. Normothermic machine perfusion (NMP) mimics the physiological state, and is conducted at 37 °C. The liver is metabolically active, allowing for ex-situ real-time assessment of viability. Hypothermic oxygenated machine perfusion (DHOPE), conducted at 4 - 14°C, has been demonstrated to improve the quality of ECD livers. This protocol is designed to assess viability of high risk donor livers using NMP, prior to transplantation. DHOPE, being superior in optimizing the quality of ECD livers will be conducted before gradually rewarming the donor liver to a normothermic temperature. During NMP a viability assessment will be carried out. Thus, high risk donor livers that would previously not have been accepted for transplantation, will be transplanted when meeting the viability criteria. Therefore, the donor pool might be expanded.

Doel van het onderzoek

1.Potentially transplantable high risk donor liver grafts can be distinguished from non-viable high risk donor liver grafts using NMP.

2.DHOPE, prior to ex situ viability assessment, increases the odds of a high risk donor liver graft to be accepted for transplantation.

Onderzoeksopzet

As described in boxes primary outcome(s) and secondary outcome(s)

Onderzoeksproduct en/of interventie

Each high risk donor liver accepted for this study will undergo machine perfusion. First, DHOPE will take place, before gradually rewarming the donor liver to a normothermic temperature. Secondly, after rewarming, NMP will be performed to allow graft assessment.

Contactpersonen

Publiek

UMCG
Y. de Vries
Groningen
The Netherlands
36305020235

Wetenschappelijk

UMCG
Y. de Vries
Groningen
The Netherlands
36305020235

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Recipient

-Adult patients (≥ 18 years old)

-Given informed consent

Donor grafts

-Donors with a body weight ≥40 kg

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Recipient

-Simultaneous participation in another clinical trial that might possibly influence this trial

-Mental conditions rendering the subject incapable to understand the nature, scope and consequences of the trial

-Listed for liver transplantation due to fulminant liver failure or retransplantation because of PNF

-Recipient tested positive for HIV

Donor grafts

-Donor tested positive for HIV, Hepatitis B or C

-Split or partial liver grafts

-Domino donor livers

-Expected cold ischemia time of ≥ 10 hours (4)

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm

Controle: N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-09-2016
Aantal proefpersonen:	10

Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	19-07-2016
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL5817
NTR-old	NTR5972
Ander register	- : 201600417

Resultaten