Hypothermic Oxygenated Perfusion of Liver Grafts Donated after Circulatory Death in Liver Transplantation - A Phase 1 Clinical Trial

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Two hours of end-ischemic hypothermic oxygenated perfusion via both the hepatic artery and the portal vein is feasible and safe in resuscitating liver grafts procured from donation after circulatory death donors.

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

Samenvatting

ID

NL-OMON19926

Bron
NTR

Aandoening

Patients with endstage liver disease who undergo liver transplantation with a graft from donation after circulatory death (DCD) donor

Dutch: Patiënten met eindstadium leverfalen die een lever transplantatie ondergaan met een lever afkomstig van een donor overleden na circulatiestilstand

Ondersteuning

Primaire sponsor: University Medical Center Groningen
Hanzeplein 1
P.O. Box 30.001
9700 RB Groningen
The Netherlands

Overige ondersteuning: funding = initiator = sponsor

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The primary endpoint of this trial will be graft survival within six months after DCD liver transplantation.

Toelichting onderzoek

Achtergrond van het onderzoek

This is a single center, prospective, non-randomized phase-I clinical trial to evaluate safety and feasibility of two hours of hypothermic oxygenated perfusion via portal vein and hep.atic artery at the end of static cold storage and before implantation. Six DCD liver grafts that are accepted for transplantation will be subjected to the intervention and the recipients will be followed for duration of six months posttransplantation. Primary endpoint is graft survival within six months

Doel van het onderzoek

Two hours of end-ischemic hypothermic oxygenated perfusion via both the hepatic artery and the portal vein is feasible and safe in resuscitating liver grafts procured from donation after circulatory death donors.

Onderzoeksopzet

- At patient inclusion

- Before liver transplantation

- Before hypothermic machine perfusion

- After hypothermic machine perfusion

- After reperfusion in the patient

- Posttransplantation at day 0 - 7, day of discharge, 1 month, 3 months and 6 months

Onderzoeksproduct en/of interventie

Liver grafts transported to the transplantation hospital will be subjected to hypothermic oxygenated machine perfusion via the portal vein and hepatic artery after static cold storage and prior to implantation. The graft will be perfused for two hours using 3L of machine perfusion solution- Belzer UW® (Bridge-to-Life, Ltd., Northbrook, IL, USA) with added glutathione (3 mmol/L). The system will be temperature (10¡ã-12¡ãC) and pressure controlled with the pressures limited to a mean of 25 mmHg at the hepatic artery and 3 mmHg at the portal vein.

In this trial the Liver Assist® (Organ Assist, Groningen, The Netherlands) will be used as perfusion machine.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen

(Inclusiecriteria)

Adult patients (> 18 years old) awaiting a liver transplantation and who have been allocated a liver graft from a DCD (Maastricht type 3) donor with a body weight of > 40 kg

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Patients with mental conditions rendering then incapable to understand the nature, scope and consequences of the trial; listed as high urgency; positive test for HIV; pregnant or nursing; donor positive for hepatitis B or C; expected cold ischemia time of > 8 hours

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 gestopt
(Verwachte) startdatum:	06-04-2014
Aantal proefpersonen:	6
Type:	Werkelijke startdatum

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

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	NL4255
NTR-old	NTR4493
Ander register	METc UMCG Groningen : M14.152454

Resultaten