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

No registrations found.

Ethical review	Not applicable
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON19926

Source
NTR

Health condition

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

Sponsors and support

Primary sponsor: University Medical Center Groningen
Hanzeplein 1
P.O. Box 30.001
9700 RB Groningen
The Netherlands
Source(s) of monetary or material Support: funding = initiator = sponsor

Intervention

Outcome measures

Primary outcome

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

Secondary outcome

- Events during liver perfusion such as technical problems, duration of additional cold ischemia time

- Intraoperative events such as reperfusion syndrome, intraoperative blood loss or need for blood products transfusions

- Histology and ATP-content of liver and bile duct biopsies at the end of cold storage, after machine perfusion and after reperfusion

- Serum levels of ALT, AST, AlkP, ¦ÃGT, LDH, total bilirubin, albumin, total protein, sodium, potassium, calcium, CRP, INR, APTT, PT, fibrinogen, creatinine and urea measured during the first week after transplantation, before discharge, and at one, three, and six months after transplantation

- Post-transplant outcomes such as need for re-transplantation, duration of ICU and hospital stay

- Postoperative complications graded according to the Clavien-Dindo classification

- Reason, number, and duration of readmission within six months after transplantation

- Incidence of clinical and asymptomatic diagnosis of NAS within six months after transplantation confirmed by at least one imaging modality of the bile duct such as endoscopic retrograde cholangiopancreatography (ERCP), magnetic resonance cholangiopancreatography (MRCP), percutaneous transhepatic cholangiogram (PTC) or conventional cholangiography

- Number and type of interventions needed due to occurrence of NAS such as ERCP or re-transplantation within six months after transplantation

Study description

Background summary

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

Study objective

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.

Study design

- 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

Intervention

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.

Contacts

Public
University Medical Center Groningen
Department of Surgery
Section HPB Surgery and Liver Transplantation
P.O. Box 30.001

R. Rijn, van
Groningen 9700 RB
The Netherlands
+31652724616
Scientific
University Medical Center Groningen
Department of Surgery
Section HPB Surgery and Liver Transplantation
P.O. Box 30.001

R. Rijn, van
Groningen 9700 RB
The Netherlands
+31652724616

Eligibility criteria

Inclusion criteria

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

Exclusion criteria

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

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	06-04-2014
Enrollment:	6
Type:	Actual

Ethics review

Not applicable

Application type:	Not applicable

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
NTR-new	NL4255
NTR-old	NTR4493

Register	ID
Other	METc UMCG Groningen : M14.152454

Study results