Diagnostic accuracy of Continuous Doppler Registration for early detection of hepatic artery thrombosis after liver transplantation

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Determine feasibility and reliability of CDFM in relation to the current strategy of intermittent Doppler US examinations for detection of hepatic artery thrombosis.

Ethical review	Approved WMO
Status	Pending
Health condition type	Other condition
Study type	Observational invasive

Summary

ID

NL-OMON30254

Source
ToetsingOnline

Brief title
Continuous Doppler Registration: CONDOR

Condition

- Other condition

Synonym
arterial occlusion

Health condition

transplantaat falen door vasculaire complicatie

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: Ministerie van OC&W,ZonMW innovatiefonds

Intervention

Keyword: doppler, hepatic artery, liver, thrombosis, transplantation, ultrasonography

Outcome measures

Primary outcome

Feasibility and reliability of CDFM for detection of HAT during the first 10

days after liver transplantation.

Secondary outcome

(1) time gain obtained by immediate recognition of HAT by the CDFM versus the

scheduled next routine Doppler US,

(2) calculation of cost and time investments of the routine investigations

performed with the current protocol as compared to CDFM,

(3) can changes in wave patterns of the CDFM predict the occurrence of HAT

(4) evaluation of side effects of implantable CDFM system

Study description

Background summary

Liver transplantation is the only life-saving treatment for patients with end-stage liver failure. About 7% of the transplanted grafts are lost mainly because of hepatic artery thrombosis (HAT), for which an early retransplantation (ReTx) must be performed. ReTx is associated with extra morbidity and mortality of the recipients and adds an extra burden to the shortage of suitable donor organs. ReTx can be avoided if vascular complications could be detected early and adequate measurements can be taken to revascularise the transplanted graft. Currently screening for HAT is performed by routine percutaneous Doppler ultrasound (US)examinations at various time

points after transplantation. In case of suspected vascular complications (CT)angiography is performed to confirm the suspicion. Percutaneous Doppler US is associated with high false positive and false negative results, and the delay in diagnosis by performing Doppler US at time intervals of several days often precludes a successful revascularisation.
In the proposed study a miniature Doppler US probe will be located in close apposition to the artery at the end of the operation, and a continuous flow measurement (CDFM) will be performed by connecting the probe to an external alarming and registration system. The accuracy of this CDFM will be compared to the standard postoperative Doppler US examinations performed according to protocol.

Intervention: During liver transplantation the miniature Doppler probe will be placed in close apposition to the hepatic artery. During the first 10 post-operative days flow signals are continuously registered. Audible and visible alarm signals will be generated when the signal drops below a certain level. If the CDFM registers a HAT, an immediate Doppler US and (if also no signal detected) a (CT) angiography will be performed for detecting vascular complications. If HAT is then confirmed an urgent revascularisation operation will follow.
Main study parameters/endpoints: (1) accuracy (true positive and true negative rate) of the CDFM versus current protocol, (2) time gain obtained by immediate recognition of HAT by the CDFM versus the scheduled next routine Doppler US, (3) number of grafts with HAT which can be rescued by immediate surgical revascularisation attempts
Burden and risks associated with participation: The minature probe has the configuration and size of routinely placed drains in the abdomen after transplantation. The disadvantage for the patient is the alarming and extra investigational procedures if a (false) negative result is obtained. Children will be included in the study because of the higher risk of HAT in pediatric liver transplantation. Withdrawal of the probe is the same as withdrawal of abdominal drains, and takes place at the ward.

Study objective

Determine feasibility and reliability of CDFM in relation to the current strategy of intermittent Doppler US examinations for detection of hepatic artery thrombosis.

Study design

prospective observational study with invasive measurements

Study burden and risks

The risk of implantation and positioning of the minaiture Doppler probe is considered to be very low. The catheter containing the Doppler probe and cabling is one of the (at least) three catheters left in the abdomen after liver transplantation. These consist of a bile drain, a feeding tube in the small bowel and one ore more drains for removal of abdominal fluid (ascites). The main disadvantage for the patient is the more frequent percutaneous Doppler US examinations performed by the radiologist. This occurs if the CDFM system detects a disturbance of the arterial flow. This is only disadvantageous for the patient if the alarm is false, and the artey proves to be open on Doppler US examination. If however the alarm detects an arterial problem which proves to be correct the patient will have benefits from it, because an urgent reoperation is performed with the aim to reopen the thrombosed artery and save the liver graft..

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)

Adults (18-64 years)
Children (2-11 years)
Elderly (65 years and older)

Inclusion criteria

Patients qualifying for the waiting list for liver transplantation

Exclusion criteria

None

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-01-2007
Enrollment:	90
Type:	Anticipated

Medical products/devices used

Generic name:	implantable Doppler probe
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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	NL14020.042.06