Hemostasis in pediatric patients undergoing orthotopic liver transplantation: a prospective cohort study.

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To assess hemostatic balance in pediatric patients before, during and after liver transplantation by comparing routine diagnostic laboratory tests with more advanced tests such as thromboelastography and thrombin generation tests.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Hepatic and hepatobiliary disorders
Study type	Observational invasive

Summary

ID

NL-OMON45316

Source
ToetsingOnline

Brief title
HIP-OLT

Condition

- Hepatic and hepatobiliary disorders
- Hepatobiliary therapeutic procedures

Synonym
coagulation, hemostasis, reducing bleeding mechanism

Research involving
Human

Sponsors and support

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

Intervention

Keyword: - Coagulation, - Hemostasis, - Liver transplantation, - Pediatric

Outcome measures

Primary outcome

Routine diagnostic tests of hemostasis (platelet count, prothrombin time),

thrombin generation tests, and thromboelastography.

Secondary outcome

Not applicable.

Study description

Background summary

In both adult and pediatric patients with end-stage liver disease the only curative treatment is liver transplantation. Both bleeding and thrombosis can complicate pediatric liver transplantation and contributing to significant morbidity and mortality. Compared to adults, pediatrics are at greater risk for developing post-transplant vascular complications.
In patients with liver diseases routine laboratory tests such as the prothrombin time and the platelet count, frequently are suggestive of a hypocoagulable state, while with more sophisticated laboratory tests it has been shown that adult patients with liver disease are in hemostatic balance as a result of concurrent changes in both pro- and antihemostatic pathways. The *rebalanced hemostasis* of patients with liver disease, however, is fragile and can relatively easily be tipped toward both bleeding and thrombosis. Previous studies showed that during liver transplantation the hemostatic system changes even more as pro- and anticoagulant factors decrease even further. Up to now, little data on the hemostatic balance in pediatric patients with liver disease are available, and no data on the changes in hemostasis during pediatric liver transplantation are available.
More knowledge of the hemostatic status in pediatric patients with liver failure during and after transplantation is required to safely and efficiently

treat and prevent both bleeding and thrombotic complications in these patients.

Study objective

To assess hemostatic balance in pediatric patients before, during and after liver transplantation by comparing routine diagnostic laboratory tests with more advanced tests such as thromboelastography and thrombin generation tests.

Study design

A single center prospective cohort study.

Study burden and risks

Burden and risks of this study are negligible. Collection of blood samples will be performed from an arterial line at time points at which blood samples are also taken for routine clinical care. Therefore, no extra venapunction or intervention is necessary to obtain the blood samples required for our study in the study population. Taking these routine blood samples carries limited risks and are usually well tolerated. Blood samples from the healthy pediatrics will be taken once via venapunction during the planned anesthesia for the minor surgical procedure. Venapunction is associated with minimal discomfort and can cause local bruising.
The benefit of this study on the long term, is that participating in this trial will give both researchers and physicians better understanding of the hemostatic status in patients with liver failure during and after transplantation. This knowledge is required for a more rational approach to prevention and treatment of bleeding and thrombotic complications in these patients.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Children (2-11 years)

Inclusion criteria

Study group
- Patients that undergo orthotopic liver transplantation for any reason at the UMCG, except patients with acute liver failure
- Livers from all sort of donors will be included, including living donor livers
- In the period from june 2017 to june 2018
- Signed informed consent (patients and/or parents/guardian);Control group
- Healthy patients that undergo minor surgery at the UMCG
Minor surgery includes inguinal operations and excision of soft tissue tumours other than malignancy, like a cyst, hemangioma or lipoma.
- In the period from june 2017 to june 2018
- Matched 2:1 with the study group population for age
- Signed informed consent (patients and/or parents/guardian)

Exclusion criteria

Study group
- Age > 16 years
- No informed consent obtained
- Diagnose of acute liver failure;Control group
- Age > 16 years
- No informed consent obtained
- Any comorbidities or pre-term birth
- Use of medication that influences liver function or hemostasis
- History of thrombotic events or bleeding

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	08-09-2017
Enrollment:	60
Type:	Actual

Ethics review

Approved WMO

Date:	28-06-2017
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	NL61164.042.17

Study results

Date completed: 25-06-2019

Actual enrolment: 50

Summary results
Trial is onging in other countries