The Efficacy of Pro- and Anticoagulant Therapy in Plasma of Patients with Cirrhosis undergoing Orthotopic Liver Transplantation

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To investigate the in vitro effect of both pro- and anticoagulation therapy on thrombin generation by Calibrated Automated Thrombography in plasma from patients with cirrhosis undergoing liver transplantation.

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

Summary

ID

NL-OMON42693

Source
ToetsingOnline

Brief title
EPAC-OLT

Condition

- Hepatic and hepatobiliary disorders
- Vascular therapeutic procedures
- Embolism and thrombosis

Synonym
bleeding, Thrombosis

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: Ministerie van OC&W,Kasai Kasei Pharma, Tokyo, Japan

Intervention

Keyword: Coagulation, Hemostasis, Orthotopic Liver Transplantation, Thrombosis

Outcome measures

Primary outcome

Thrombin generation by Calibrated Automated Thrombinography.

Secondary outcome

Other study parameters are individual coagulation factors, Prothrombin Time

(PT), International Normalized Ratio (INR), Activated Partial Thromboplastin

Time (APTT), Fibrinogen, Platelet count and Hemoglobin (Hb). Moreover,

indicators of liver function such as Gamma-Glutamyl Transpeptidase (GGT),

Asparate Aminotransferase (ALT) Alanine Transaminase (AST), ammonia (NH3),

alpha1 antitrypsin and ceruloplasmin are study parameters.

Study description

Background summary

Patients with liver disease are at risk for both bleeding and thrombotic complications, and this risk further increases in patients undergoing liver transplant surgery. Little clinical data on efficacy and safety of pro- and antihemostatic drugs in patients undergoing liver transplantation are available. We aim to assess the in vitro efficacy of both pro- and anticoagulant drugs by comparing thrombin generation curves (considering thrombin generation lag time, time to peak thrombin generation, peak thrombin generation, and endogenous thrombin potential) generated in plasma taken from patients during and after liver transplantation, with thrombin generation curves generated in the plasma of healthy volunteers. Various pro- and

anticoagulant drugs will be added to these plasma samples in vitro. The percentual change in parameters of the thrombin generation curve after addition of a fixed dose of a pro- or anticoagulant drugs is the primary endpoint of the study. This study may help guide the dosage of these drugs in these patients during and after transplantation. Moreover, it may prevent overdosing with the risk of unwarranted complications (e.g. bleeding or thrombosis).

Study objective

To investigate the in vitro effect of both pro- and anticoagulation therapy on thrombin generation by Calibrated Automated Thrombography in plasma from patients with cirrhosis undergoing liver transplantation.

Study design

A prospective cohort, mono-center study.

Study burden and risks

Blood samples from the healthy volunteers will be taken once via venapunction. During the liver transplantation, blood samples will be taken at the same time blood samples for routine care will be withdrawn via an arterial line. Venapunction is associated with minor discomfort and can cause local bruising.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Orthotopic Liver Transplantation for cirrhosis at the UMCG
Age >18 years
Signed informed consent

Exclusion criteria

Acute liver failure
Documented history of hereditary thrombophilia
Use of vitamin K antagonists
Transfusion of blood products (<7 days)
Deep venous thrombosis (<30 days)

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-09-2015
Enrollment:	60
Type:	Actual

Ethics review

Approved WMO Date:	20-08-2015
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	NL53151.042.15