The efficacy of pro- and anticoagulant therapy in plasma from patients with liver cirrhosis .

Published: 06-06-2012
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To investigate the in vitro effect of pro- and anticoagulants on the hemostatic capacity of plasma from patients with liver cirrhosis.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Coagulopathies and bleeding diatheses (excl thrombocytopenic)
Study type	Observational invasive

Summary

ID

NL-OMON37417

Source
ToetsingOnline

Brief title
EPAC

Condition

- Coagulopathies and bleeding diatheses (excl thrombocytopenic)

Synonym
coagulation., hemostasis

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: Anticoagulants, Cirrhosis, Hemostasis, Procoagulants

Outcome measures

Primary outcome

The functionality of the secondary hemostatic system, as determined by thrombin

generation assays.

Secondary outcome

Not applicable

Study description

Background summary

In contrast with historical believes, several recent laboratory studies have shown a rebalanced haemostasis in patients with chronic liver disease due to a decrease in both pro- and anticoagulant drivers. However this balance can be easily tipped over to a hypercoagulable or a hypocoagulable state with the risk of both bleeding complications and clinical thrombotic events. The role of prohemostatic and antihemostatic products for the prevention and treatment of these bleeding complications and thrombotic complications, in cirrhotic patients, is unstudied or remained unclear in previous studies. We aim to assess the efficacy of procoagulant and anticoagulant therapy in vitro in plasma of cirrhotic patients. This may help guide the dosage of these drugs in cirrhotic patients and may prevent overdosing with the risk of opposite haemostatic imbalance.

Study objective

To investigate the in vitro effect of pro- and anticoagulants on the hemostatic capacity of plasma from patients with liver cirrhosis.

Study design

A cross-sectional study

Study burden and risks

Participating patients undergoing venapunction for routine laboratory measurements will donate one blood sample of 45 ml for this study. This patient group undergoes venapunction regularly as part of their routine control for their liver cirrhosis by the department of hepatology of the UMCG. Volunteers from the control group will also undergo venapunction and donate 45 ml blood. 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

Inclusion criteria study group:
- Cirrhosis
- >18 year
- Signed informed consent

Inclusion criteria healhty control group
- >18 year
- Signed informed consent

Exclusion criteria

Exclusion criteria study group:
- Congenital coagulation disorder
- Active infection
- Acute liver failure
- Use of anticoagulant drugs in the past 10 days
- Pregnancy
- HIV+
- (<7 days) transfusion with blood products;Exclusion criteria control-group
- Documented history of congenital coagulation disorder
- History of vascular disease
- History of hepatic disease
- History of any systemic disease
- Recent viral infection (>2 weeks)
- Use of anticoagulant drugs in the past 10 days
- Pregnancy

Study design

Design

Study type:	Observational 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):	06-08-2012
Enrollment:	126

Type:	Actual

Ethics review

Approved WMO Date:	06-06-2012
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	NL40435.042.12