The effects of Transjugular Intrahepatic Portosystemic Shunt placement on von Willebrand factor levels in plasma of patients with cirrhosis and portal hypertension.

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To investigate whether a decrease in portal pressure after placement of a transjugular intrahepatic portosystemic shunt results in a decline in von Willebrand factor plasma levels.

Ethical review	Approved WMO
Status	Will not start
Health condition type	Coagulopathies and bleeding diatheses (excl thrombocytopenic)
Study type	Observational invasive

Summary

ID

NL-OMON38711

Source
ToetsingOnline

Brief title
VWF-TIPS study

Condition

- Coagulopathies and bleeding diatheses (excl thrombocytopenic)

Synonym
increased pressure in the liver, portal hypertension

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: cirrhosis, portal hypertension, TIPS, von Willebrand factor

Outcome measures

Primary outcome

The level of von Willebrand factor prior to, directly after, one week after,

and one month after placement of a transjugular intrahepatic portosystemic

shunt.

Secondary outcome

Not applicable

Study description

Background summary

Patient with severe liver cirrhosis often suffer from portal hypertension resulting in ascites formation, gastroesophageal varices and variceal bleeding. Besides these hemodynamic changes, patient with cirrhosis also experience changes in the hemostatic system due to decreased synthesis and clearance of pro- and antihemostatic proteins by the liver. Von Willebrand factor (vWf) is an important prohemostatic protein involved in activation and aggregation of platelets and is synthesized by the endothelial cells and cleared by the liver. Patients with cirrhosis often have increased levels of vWF, possibly caused by decreased clearance by the cirrhotic liver. In recent years however, endothelial activation as a result of portal hypertension has been indicated as a cause of the increased vWF levels in patients with cirrhosis. Indeed, levels of vWF were shown to be an important predictor for severity of portal hypertension, severity of liver disease, and mortality. Formal proof that elevated vWF levels are a direct consequence of portal hypertension is still lacking.

Study objective

To investigate whether a decrease in portal pressure after placement of a transjugular intrahepatic portosystemic shunt results in a decline in von Willebrand factor plasma levels.

Study design

A prospective observational study.

Study burden and risks

Participating patients will donate one blood sample of 9 ml on each of the five time points. The blood sample will be collected during routine venapunction for clinical laboratory measurements.
Vena punction is associated with minor discomfort and possibly minor 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

- Patient with cirrhosis undergoing TIPS placement
- >=18 years of age
- Signed informed consent

Exclusion criteria

Patients with hemophilia A or von Willebrands disease

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	16
Type:	Anticipated

Ethics review

Approved WMO Date:	07-05-2013
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	10-02-2014

Application type:	Amendment
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	NL43487.042.13