Effects of DDAVP (1-deamino-8-D arginine vasopressin) infusion on parameters of hemostasis in patients with liver cirrhosis

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This study aims to collect biochemical evidence for the pro-hemostatic capacity of DDAVP in patients with cirrhosis, in order to proceed towards a more rational clinical use of this drug.

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

Summary

ID

NL-OMON39451

Source
ToetsingOnline

Brief title
DDAVP in cirrhosis

Condition

- Coagulopathies and bleeding diatheses (excl thrombocytopenic)
- Hepatic and hepatobiliary disorders
- Haematological and lymphoid tissue therapeutic procedures

Synonym
Liver failure, liver fibrosis

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: DDAVP, Hemostasis, Liver cirrhosis, thrombocytes

Outcome measures

Primary outcome

Study endpoint will be time-dependent changes in laboratory parameters in

patients with cirrhosis compared to these changes in patients with hemophilia,

in which the efficacy of DDAVP has been well established.

Secondary outcome

To elucidate possible mechanisms involved in the supranormal levels of VWF and

factor VIII in patients with liver cirrhosis.

Study description

Background summary

Cirrhosis of the liver may be associated with substantial alterations in the hemostatic system. Liver disease frequently affects multiple components of hemostasis including platelets, the coagulation/anticoagulation system, and the fibrinolytic system. Although both pro- and antihemostatic systems are defective in these patients, the net effect of the hemostatic changes is a bleeding tendency. Reversal of the coagulopathy of these patients is frequently required in case of bleeding episodes, or as prophylaxis before invasive procedures. A simple and cost-effective way to correct the prolonged bleeding time in patients with cirrhosis is administration of 1-deamino-8-D-arginine vasopressin (DDAVP). It is, however, unclear whether the reduction in bleeding time by DDAVP also enhances in vivo hemostasis, although DDAVP is widely used as a pro-hemostatic agent in patients with cirrhosis.

Study objective

This study aims to collect biochemical evidence for the pro-hemostatic capacity of DDAVP in patients with cirrhosis, in order to proceed towards a more rational clinical use of this drug.

Study design

Clinical observational mono-center study

Intervention

Patients will be administered a single dose of DDAVP (0.3 µg/kg, intravenously) Blood samples (10 ml, into trisodiumcitrate) will be taken just before infusion, and 1, 3, 6, and 24 hours after infusion.

Study burden and risks

A single i.v. injection with DDAVP will be given.Five blood draws of 10ml each will be taken. Side effects associated with DDAVP administration are mild and may include facial flushing (due to vasodilatation), transient headaches, 10-20% increase in heart rate, minor decrease in blood pressure, and water retention (as DDAVP is an analogue of the antidiuretic hormone vasopressin) Thrombotic episodes associated with DDAVP administration have been described, but they are extremely rare, and have never been shown to be causally related. DDAVP has been in clinical use for about 30 years.

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

Research group:
- Leeftijd > 18 yrs
- Non-cholestatic cirrhosis, with moderate to severe disease (Child B or C)
- Schedukled to visit the policlinic hepatology for routine check-up
- Informed consent
Control group (samples obtained in Erasmus MC Rotterdam for different research project)
- age>18 yrs
- hemophilia type A
- Informed consent

Exclusion criteria

- Age < 18 yrs
- Biliary cirrhosis
- Malignancies
- Renal failure requiring intervention with drugs or dialysis
- Active infection requiring intervention
- Recent (< 7 days before administration) transfusion of plasma or platelet concentrates
- Use of aspirin, other anti-platelet drugs, antifibrinolytic agents or vitamin K antagonists
- Angina Pectoris
- One of the following disorders of coagulation: hemophilia, Von Willebrand's disease, antithrombin deficiency, protein C deficiency or protein S deficiency

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-07-2012
Enrollment:	10
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Minirin
Generic name:	Desmopressin
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	27-06-2012
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	29-10-2012
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	11-06-2013
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
EudraCT	EUCTR2010-021827-28-NL
CCMO	NL40025.042.12