Prothrombin Complex Concentrate in the reduction of blood loss during orthotoppic liver transplantation.

No registrations found.

Ethical review	Not applicable
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON28249

Source
Nationaal Trial Register

Brief title
PROTON-studie

Health condition

cirrhosis
bleeding
hemorrhage
complications
hemostasis
coagulation

Sponsors and support

Primary sponsor: Sanquin Plasma Products
Source(s) of monetary or material Support: Sanquin Plasma Products.

Intervention

Outcome measures

Primary outcome

Transfusion requirements per-operative To study the hemostatic efficacy of preoperative PCC administration in patients with cirrhosis undergoing liver transplantation. The hemostatic efficacy will be primarily monitored by recording the need for RBC transfusion.

Secondary outcome

To study the hemostatic safety of preoperative PCC administration in patients with cirrhosis undergoing liver transplantation. The hemostatic safety will be monitored by adverse event surveillance and laboratory measurements, with a special focus on thrombogenicity.

Study description

Background summary

In the past decaded, peroperative blood loss and transfusion requirements for cirrhotic patients undergoing liver transplantation have decreased significantly. This is mostly due to restrictive transfusion policy and refinement of surgical and anesthesiological procedures. Major bleeding complications can still occur however. Where cirrhotic patients were used to be considered auto-anticoagulated in the past, due to prolonged conventional coagulation test, its clear in the present dat these coagulation test do not present us with accurate information about the hemostatic ability and dont predict transfusion requirements. Correction of the prolonged coagulation test does not lead to less bleeding.

Study objective

Intravenous administration of cofact pre-operatively, will reduce the amount of bloodloss and the transfusion requirements in cirrhotic patients undergoing liver ransplantation.

Study design

Januari/februari: First inclusion.

2 years to inlcude 140 patients.

Follow-up of patients: Day 1 till 7 postoperative, day 9, day 11, day 30.

Intervention

The intervention is the intravenous administration of de studyproducts. Depending in which group the patients is randomized, he or she will receive either the placebo (NaCl) or Cofact/ Prothrombin Complex Concentrate. The intervention will take place 30 minutes before start of surgery. De studyproduct will be administered at a rate of 2ml/min, depending on the amount this wil take up to 15 minutes. After this the surgical procedure, othotopic liver transplantation, wil be initiated. We will monitor the amount fo blood loss and amount and type of infusion products administered during the surgical procedures. This includes transfusion of Red Blood Cell's, Fresh Frozen Plasma and also other transfusions such as hemostatic products. After 140 patients are included, we will collect all data to determine what the mean blood loss was in the placebo group versus the studygroup. At the moment, the mean transfused units of Red Blood Cell in participating centra is 8 with a standarddeviation of 4 units. We will perform statistical analysis to determine wether the patients that received Prothrombin Complex Concentrate have a significant decrease in blood loss and transfusion requirements compared to the placebo group. Hereby we can determine wether Prothrombin Complex Concentrate decereases or even prevents blood loss in patient with liver cirrhosis who are undergoing orthotopic liver transplantation.

Contacts

Public
Secretariaat Hepatobilaire chirurgie (secretary hepatobilair surgery) UMCG
Afdeling Chirurgie, BA33
Postbus 30.001
F. Arshad
Groningen 9700 RB
The Netherlands
+31 (0)50 3612896
Scientific
Secretariaat Hepatobilaire chirurgie (secretary hepatobilair surgery) UMCG
Afdeling Chirurgie, BA33
Postbus 30.001
F. Arshad
Groningen 9700 RB
The Netherlands
+31 (0)50 3612896

Eligibility criteria

Inclusion criteria

1. 18y;

2. Cirrhosis, scored as Child-Turcotte- Pugh class B or C or > 13 or as model of end-stage liver disease (MELD) score of > 20;

3. INR>1.5;

4. Signed informed consent.

Exclusion criteria

1. Previous liver transplantation;

2. Split liver transplantation;

3. Heterotopic liver transplantation;

4. Scheduled multiorgan transplantation;

5. Scheduled living related-donor transplantation;

6. Renal insufficiency requiring dialysis;

7. Documented congenital coagulation disorders;

8. Documented history or presence of portal vein thrombosis;

9. Treatment with warfarin;

10. TIPS (transjugular intrahepatic portosystemic shunt);

11. Fulminant hepatitis;

12. Coronary artery disease;

13. History of thrombophilia (e.g. FVLeiden mutation).

Study design

Design

Study type:	Interventional
Intervention model:	Parallel

Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	20-01-2012
Enrollment:	140
Type:	Anticipated

Ethics review

Not applicable

Application type:	Not applicable

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
NTR-new	NL3026
NTR-old	NTR3174
Other	METC-UMCG : MD2011.01
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A