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

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

Ethische beoordeling	Niet van toepassing
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON28249

Bron
Nationaal Trial Register

Verkorte titel
PROTON-studie

Aandoening

cirrhosis
bleeding
hemorrhage
complications
hemostasis
coagulation

Ondersteuning

Primaire sponsor: Sanquin Plasma Products
Overige ondersteuning: Sanquin Plasma Products.

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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

Onderzoeksopzet

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.

Onderzoeksproduct en/of interventie

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.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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).

Onderzoeksopzet

Opzet

Type: Interventie onderzoek

Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	Placebo

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	20-01-2012
Aantal proefpersonen:	140
Type:	Verwachte startdatum

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL3026
NTR-old	NTR3174
Ander register	METC-UMCG : MD2011.01
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A