Transjugular Intrahepatic Porto-systemic Shunt (TIPS) with Gore-tex(R) covered stent-graft versus endoscopic treatment for secondary prevention of gastro-esophageal variceal bleeding.

Gepubliceerd: 16-05-2007 Laatst bijgewerkt: 13-12-2022

TIPS using covered stents will be equally or more effective, cost-effective and safe as/than endoscopic treatment in the secondary prevention of gastro-esophageal variceal bleeding.

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON21706

Bron
NTR

Verkorte titel
TIPS TRUE

Aandoening

TIPS, endoscopic treatment, variceal bleeding
(TIPS, endoscopische behandeling, varices bloedingen)

Ondersteuning

Primaire sponsor: Erasmus MC, department of Radiology and Department of Gastro-enterology
Overige ondersteuning: ZonMw and Erasmus MC

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Recurrence of variceal bleeding

Toelichting onderzoek

Achtergrond van het onderzoek

Patients with liver cirrhosis and bleeding from gastro-esophageal varices are currently largely treated with endoscopic (variceal band ligation; tissue glue injection) therapy. When this treatment, the accepted second-line treatment is radiological creation of a Transjugular Intrahepatic Porto-systemic Shunt (TIPS). Previous studies comparing endoscopic therapy with TIPS found that TIPS is more effective in reducing the risk of recurrent variceal bleeding but is associated with a higher risk of hepatic encephalopathy and does not improve survival. Recently, the efficacy of TIPS has been remarkedly improved by using covered stents. These stents significantly decrease the risk of shunt obstruction, which was the main problem with TIPS using conventional, bare stents. Given the probably significantly improved efficacy of TIPS with covered stents, this trial will re-assess the question whether TIPS might be superior (concerning efficacy and cost-effectiveness) to endoscopic procedures when performed early after a first or second episode of gastro-esophageal bleeding.

Doel van het onderzoek

TIPS using covered stents will be equally or more effective, cost-effective and safe as/than endoscopic treatment in the secondary prevention of gastro-esophageal variceal bleeding.

Onderzoeksopzet

-

Onderzoeksproduct en/of interventie

Transjugular Intrahepatic Porto-systemic Shunt (TIPS)(intervention group): a shunt is made between the portal vein and the systemic veins, which decreases blood pressure in the portal vein to normal. This decreases the risk of re-bleeding. The procedure takes approximately 2 hours.
Endoscopic treatment (control group): the bleeding varices are ligated or sclerosed. The pressure in the portal vein remains too high. This procedure has to be repeated several times until the varices are completely obliterated.

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Patients presenting with a first or second episode of esophageal or gastric variceal bleeding, as documented by endoscopy and meeting accepted diagnostic criteria;
2. Initial stabilization (absence of evidence of continued bleeding);
3. Informed consent;
4. Age > 18 and < 76 years

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. History of serious or refractory encephalopathy, unrelated to gastrointestinal bleeding;
2. History of significant heart failure (NYHA class III & IV);
3. Portal hypertension due to other causes than liver disease (e.g. portal vein or splenic vein thrombosis);
4. Previous TIPS placement;
5. Advanced hepatocellular carcinoma;
6. Severely compromised liver function (Child-Pugh score >13);
7. Sepsis and/or multiorgan failure

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-06-2007
Aantal proefpersonen:	72
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	16-05-2007
Soort:	Eerste indiening

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	NL948
NTR-old	NTR973
Ander register	- : -
ISRCTN	ISRCTN77521636

Resultaten