

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

No registrations found.

<b>Ethical review</b>	Positive opinion
<b>Status</b>	Pending
<b>Health condition type</b>	-
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON21706

### Source

NTR

### Brief title

TIPS TRUE

### Health condition

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

## Sponsors and support

**Primary sponsor:** Erasmus MC, department of Radiology and Department of Gastroenterology

**Source(s) of monetary or material Support:** ZonMw and Erasmus MC

## Intervention

## Outcome measures

### Primary outcome

Recurrence of variceal bleeding

### Secondary outcome

1. Occurrence of treatment failure (either switch to other therapy -“cross-over”- or death);
2. Incidence of encephalopathy, defined as occurrence of grade II, III or IV encephalopathy;
3. Liver function (according to Child-Pugh class);
4. Mortality;
5. Quality of life;
6. Costs

## Study description

### Background summary

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 remarkably 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.

### Study objective

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.

### Study design

-

### Intervention

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.

## Contacts

### Public

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### Scientific

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## Eligibility criteria

### Inclusion criteria

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

## Exclusion criteria

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

## Study design

### Design

Study type:	Interventional
Intervention model:	Parallel
Masking:	Open (masking not used)
Control:	Active

### Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	01-06-2007
Enrollment:	72
Type:	Anticipated

### IPD sharing statement

**Plan to share IPD:** Undecided

## Ethics review

Positive opinion	
Date:	16-05-2007
Application type:	First submission

## 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	NL948
NTR-old	NTR973
Other	- : -
ISRCTN	ISRCTN77521636

## Study results