# Transjugular Intrahepatic Porto-systemic Shunt (TIPS) with Gore-tex covered stent-graft versus endoscopic treatment for acute bleeding of esophageal varices.

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| **Ethical review** | Approved WMO |
| **Status** | Recruiting |
| **Health condition type** | Hepatic and hepatobiliary disorders |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON39467

**Source**
ToetsingOnline

**Brief title**
TIPS bleeding

### Condition

- Hepatic and hepatobiliary disorders

**Synonym**
bleeding of esophageal varicose veins, portal hypertension

**Research involving**
Human

### Sponsors and support

**Primary sponsor:** Erasmus MC, Universitair Medisch Centrum Rotterdam

**Source(s) of monetary or material Support:** Ministerie van OC&W

## Intervention

**Keyword:** bleeding, endoscopy, esophageal varices, TIPS

## Outcome measures

### Primary outcome

Recurrence of bleeding

### Secondary outcome

Initial technical success in staunching bleeding.

Child Pugh classification.

Incidence of encephalopathy.

Mortality.

Medical costs.

Non-medical costs.

# Study description

### Background summary

Currently, patients with acute bleeding of esophageal varices are treated with local band ligation and/or sclerosing of the bleeding vessel under endoscopic guidance. An alternative treatment is creation of a Transjugular Intrahepatic Porto-systemic Shunt (TIPS) with a Gore-tex covered stent-graft. This is a radiographically-guided, minimally invasive procedure that not only staunches the bleeding, but also treats the underlying cause, increased blood pressure in the portal vein. In this prospective clinical trial, we seek to compare these two treatment options with regard to efficacy and cost-effectiveness.

### Study objective

The aim of this study is to compare the new (covered) TIPS stent with the standard treatment, local band ligation and/or sclerosing of the bleeding vessel under endoscopic guidance, in patients with acute bleeding of esophageal

varices, with regard to efficacy and cost-effectiveness. The theory is that using the TIPS not only staunches the bleeding but also treats the underlying cause, increased blood pressure in the portal vein. Therefore the risk of rebleeding decreases. On the contrary endoscopy staunches the bleeding, but does not treat the underlying cause. Therefore there is a high risk of rebleeding.

## Study design

In total 124 patients, divided over 3 hospitals in the Netherlands, will take part in the study. The study is started from the Erasmus Medical Center in Rotterdam. Furthermore patients from the Academical Medical Center in Amsterdam and the Leiden University Medical Center will participate.
To determine whether one treatment option is better than the other, stratified randomisation is used. The participants will be randomized into two groups, taking into acount the Child Pugh Classification (a scoring system of liver disease severity). Whether TIPS is more effective than the common used therapy, local band ligation and/or sclerosing of the bleeding vessel under endoscopic guidance, can be discovered by comparing the groups.
The participants will have the routinely controls for patients with bleeding varicose veins. Within the scope of the study they will be followed for one year.
The study will continue for 2 years, one year in which patients will be asked to participate, and one year to follow the last participants.

## Intervention

TIPS (Transjugular Intrahepatic Portosystemic Shunt) procedure:

Through a vein in the neck, a small tube (stent) is placed between two veins in the liver to decompress the veins of the liver.

## Study burden and risks

TIPS-procedure:
TIPS will be performed under general anesthesia. Nausea and vomiting after waking are less frequent with the current medication techniques, but might occur. During the first hours after anesthesia some problems concerning memory or concentration might arise.
Because of intubating ( to ensure the respiration during the intervention)dental damage by the tube could arise. Unforeseen complications, which are life threatening, like a grave allergy, cardiac arrest, or respiration arrest are very rare, and they occur in less than 3 out of 10.000 anesthesias. The stent will be placed between the veins in the liver through a vein in the neck. The place in the neck where this is done might get a bruise after the intervention. Some days after the intervention pain from the veins

may be perceived. This will disappear spontaneously. Other complications that might occur after the TIPS-procedure, are temporal cardiac arrhythmias, jaundice and fever. In rare cases puncture of the liver capsule with the needle can occur and blood might flow into the abdominal cavity, but usely this has no major consequences.
TIPS increases the risk of hepatic encephalopathy. This is confusion and dullness related to the liver disease. When this happens it might be neccesary to close the stent, to decline the disturbances. Within the scope of TIPS-procedure patients will be hopitalized standardly; this will take some days.

Participation in the study means that the patient will be followed for one year in view of the study. This will be done by the regular controls which are usual for patients with esophageal varices. At month 3, 6, 9 and 12 the patient will get a questionnaire and blood will be taken.

Burden and risks of conventional therapy (local band ligation and/or sclerosing of the bleeding vessel under endoscopic guidance):
During the year patient will undergo this treatment again, every time he rebleeds. For the initial stabilization and the first endoscopic treatment patients will be hospitalized standardly. The follow-up endoscopic treatment will be take place out patients.

## 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

Acute or subacute bleeding of esophageal varices as documented with diagnostic endoscopy.
Initial stabilization, as achieved by using octreotide infusion and endoscopic ligation of the major bleeding vessel, and placement of a Sengstaken tube in patients in whom the former combination treatment fails to stop the bleeding.
Informed consent.

### Exclusion criteria

Serious or untreatable encephalopathy.
Heart failure.

## Study design

### Design

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| Study type: | Interventional |
| Intervention model: | Parallel |
| Allocation: | Randomized controlled trial |
| Masking: | Open (masking not used) |
| Control: | Active |
| Primary purpose: | Treatment |

### Recruitment

NL

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|---|---|
| Recruitment status: | Recruiting |
| Start date (anticipated): | 23-04-2007 |
| Enrollment: | 72 |
| Type: | Actual |

## Ethics review

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| Approved WMO Date: | 12-04-2007 |
| Application type: | First submission |
| Review commission: | METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam) |
| Approved WMO Date: | 03-05-2013 |
| Application type: | Amendment |
| Review commission: | METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam) |

## 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 |
|---|---|
| CCMO | NL14150.078.06 |