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

Submission date 30/05/2007	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 30/05/2007	**Overall study status** Completed	
Last Edited 21/09/2007	**Condition category** Digestive System	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
N/A

Study information

Scientific Title

Study objectives
Transjugular Intrahepatic Porto-systemic Shunt (TIPS) using covered stents will be equally or more effective, cost-effective and safe as/safer than endoscopic treatment in the secondary prevention of gastro-oesophageal variceal bleeding.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from the local medical ethics committee

Study design
Randomised, multicentre, active controlled, parallel group trial

Primary study design
Interventional

Study type(s)
Diagnostic

Health condition(s) or problem(s) studied
Gastro-oesophageal variceal bleeding

Interventions
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 two 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.

Intervention Type
Other

Phase
Not Specified

Primary outcome(s)
Recurrence of variceal bleeding

Key secondary outcome(s))
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

Completion date
01/06/2009

Eligibility

Key inclusion criteria
1. Patients presenting with a first or second episode of oesophageal or gastric variceal bleeding, as documented by endoscopy and meeting accepted diagnostic criteria
2. Initial stabilisation (absence of evidence of continued bleeding)
3. Informed consent
4. Aged more than 18 and less than 76 years

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Not Specified

Sex
Not Specified

Key exclusion criteria
1. History of serious or refractory encephalopathy, unrelated to gastrointestinal bleeding
2. History of significant heart failure (New York Heart Association [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 greater than 13)
7. Sepsis and/or multiorgan failure

Date of first enrolment
01/06/2007

Date of final enrolment
01/06/2009

Locations

Countries of recruitment
Netherlands

Study participating centre
Erasmus Medical Centre
Rotterdam
Netherlands
3015 CE

Sponsor information

Organisation
Erasmus Medical Centre (The Netherlands)

ROR
https://ror.org/018906e22

Funder(s)

Funder type
Research organisation

Funder Name
The Netherlands Organisation for Health Research and Development (ZonMw) (The Netherlands)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration