

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	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 30/05/2007	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 21/09/2007	Condition category Digestive System	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Diagnostic

Participant information sheet

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 measure

Recurrence of variceal bleeding

Secondary outcome measures

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

Overall study start date

01/06/2007

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

Age group

Not Specified

Sex

Not Specified

Target number of participants

124

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)

Sponsor details

Department of Radiology

Dr. Molewaterplein 50

Rotterdam

Netherlands

3015 GE

Sponsor type

Hospital/treatment centre

Website

<http://www.erasmusmc.nl/content/englishindex.htm>#<http://www.erasmusmc.nl/content/englishindex.htm>

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

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration