

Covered transjugular intrahepatic portosystemic stent shunt versus optimised medical treatment for the secondary prevention of variceal bleeding in cirrhosis

Submission date 26/01/2006	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 22/03/2006	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 15/06/2017	Condition category Digestive System	<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
2005-003557-27

Protocol serial number
SA-388-4-1

Study information

Scientific Title

Covered transjugular intrahepatic portosystemic stent shunt versus optimised medical treatment for the secondary prevention of variceal bleeding in cirrhosis

Study objectives

The objective of this trial is to show that an intrahepatic shunt by insertion of a small-diameter polytetrafluoroethylene (PTFE) covered stent (cTIPS) is the superior method for secondary prevention of variceal bleeding in cirrhosis when compared to an optimised standard treatment that includes hemodynamically monitored drug treatment (propranolol and isosorbide-5-mononitrate [IsMn]) or endoscopic banding ligation in haemodynamic non-responders.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics Committee of the University of Bonn, 23/01/2006, ref: 110/05

Study design

Randomised controlled open multicentre trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Liver cirrhosis

Interventions

PTFE-coated TIPS versus optimized medical treatment including drug treatment with propranolol and isosorbide-5-mononitrate with or without ligation

Intervention Type

Drug

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Propranolol, isosorbide-5-mononitrate

Primary outcome(s)

Re-bleeding incidence

Key secondary outcome(s))

1. Overall survival
2. Safety

3. Quality of life
4. Direct and indirect costs

Completion date

01/09/2010

Eligibility

Key inclusion criteria

1. Liver cirrhosis (histological or clinical diagnosis)
2. Child-Pugh score less than 12
3. Serum bilirubin less than 3 mg/dl
4. Significant variceal bleeding greater than 5 days prior to randomisation
5. Clinical indication for re-bleeding prophylaxis (i.e. presence of esophageal varices greater than or equal to grade 2)
6. Age 18 to 75
7. Written informed consent signed and dated by patient and investigator

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Key exclusion criteria

1. Overt hepatic encephalopathy independent from bleeding
2. Pre-hepatic portal hypertension
3. Type II gastric varices as exclusive bleeding site
4. Established chronic drug treatment with beta-blockers and/or nitrates against portal hypertension
5. Listing for liver transplantation on T2 status
6. Existing porto-systemic shunt (TIPS or surgical shunt)
7. Heart failure according to the New York Heart Association (NYHA) classification greater than 2 or ejection fraction less than 40%
8. Contraindication against propranolol or nitrates
9. Platelet count less than 30 g/l, prothrombin index less than 30%, disseminated intravascular coagulation
10. Advanced malignancy or severe infection
11. Females of child bearing potential not using a safe contraceptive measure during the study or females with a positive pregnancy test prior to study or nursing women

Date of first enrolment

01/03/2006

Date of final enrolment

01/09/2010

Locations

Countries of recruitment

Germany

Study participating centre

Sigmund-Freud-Str. 25

Bonn

Germany

53105

Sponsor information

Organisation

Individual sponsor (Germany)

Funder(s)

Funder type

Research council

Funder Name

Deutsche Forschungsgemeinschaft (ref: DFG-AZ 60665-02-2/401/04)

Alternative Name(s)

German Research Association, German Research Foundation, Deutsche Forschungsgemeinschaft (DFG), DFG

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

Germany

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/09/2015		Yes	No