

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

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| 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

EudraCT/CTIS number
2005-003557-27

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use the contact details to request a patient information sheet

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)

Propanolol, isosorbide-5-mononitrate

Primary outcome measure

Re-bleeding incidence

Secondary outcome measures

1. Overall survival
2. Safety
3. Quality of life
4. Direct and indirect costs

Overall study start date

01/03/2006

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

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

186 (93 per group)

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

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Sponsor information

Organisation

Individual sponsor (Germany)

Sponsor details

Prof Dr Büttner

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Sponsor type

Research organisation

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, DFG

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

Germany

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

Study outputs

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