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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

Registration date
22/03/2006

Overall study status
Completed

Last Edited
15/06/2017

Condition category
Digestive System

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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 propanolol 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 propanolol 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
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Sponsor information

Organisation
Individual sponsor (Germany)

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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