ClinicalTrials.gov Protocol and Results Registration System (PRS) Receipt
Release Date: 04/08/2015

ClinicalTrials.gov ID: NCT00593528

Study Identification

Unique Protocol ID: STIC07-JMP/TIPS-PTFE

Brief Title: PTFE Covered Stents Versus Naked Stents in the TIPS (Transjugular Intra-hepatic Porto-systemic Shunt)

Official Title: Randomized Study With Medico-economic Evaluation Comparing the Use of PTFE Covered Stents vs Naked Stent in the TIPS (Transjugular Intra-hepatic Porto-systemic Shunt)

Secondary IDs: 2007-A00857-46 [EudraCT Number]

Study Status

Record Verification: April 2015

Overall Status: Completed

Study Start: February 2008

Primary Completion: July 2011 [Actual]

Study Completion: July 2011 [Actual]

Sponsor/Collaborators

Sponsor: University Hospital, Tours

Responsible Party: Sponsor

Collaborators:

Oversight

FDA Regulated?: No

IND/IDE Protocol?: No

Review Board: Approval Status: Approved
Approval Number: 2007-R40
Board Name: CPP Tours (Ouest-1)
Board Affiliation: Comité de Protection des Peronnes (CPP)
Phone: (33) 2-47-47-82-21
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Data Monitoring?: No

Plan to Share Data?:

Oversight Authorities: France: Afssaps - Agence française de sécurité sanitaire des produits de santé (Saint-Denis)

Study Description

Brief Summary: Transjugular intrahepatic portosystemic shunts (TIPS) have been increasingly used for the treatment of complications of portal hypertension in patients with cirrhosis.

The initial experiment of the TIPS was reported during the 1990s with stents of various brands, manufacture and sizes, but all "non covered", thus owing the pseudointimal hyperplasia growing inside the stent, which progressively decreases the diameter of the shunt and thus its efficacy. Since the beginning of the 2000s, appeared stents known as "covered" by polytetrafluoroethylene (PTFE) designed to reduce the obstruction rate and thus the frequency shunt revisions. However, these stents are, on average, 2.5 times more expensive than the non covered stents and the cost-effectiveness ratio of the TIPS according to the type of stents used has not been assessed.

The aim of this multicentric and randomized study is to assess the cost-effectiveness ratio of these 2 principles of TIPS, the one using stents covered by PTFE, relatively expensive but seldom becoming obstructed, and the other using non covered stents, less expensive than PTFE but requiring regular gestures of redilatation.

Population concerned: Patients with a cirrhotic portal hypertension responsible for:

- recurrent variceal bleeding
- refractory ascite (or hydrothorax)

Detailed Description:

Conditions

Conditions: Cirrhotic Portal Hypertension

Keywords: Cirrhosis, STIC TIPS, Portal Hypertension, Transjugular Intrahepatic Portosystemic Shunt , Stents, PTFE
cirrhotic HTP

Study Design

Study Type: Interventional

Primary Purpose: Treatment

Study Phase: N/A

Intervention Model: Parallel Assignment

Number of Arms: 2

Masking: Open Label

Allocation: Randomized

Endpoint Classification: Efficacy Study

Enrollment: 138 [Actual]

Arms and Interventions

Arms	Assigned Interventions
Active Comparator: A Naked Stents	Device: Naked Stents: Wallstent® (Boston Scientific), Luminexx® (Bard), Zilver® (Cook), Palmaz Genesis® and Smart Control® (Cordis) Vascular Stents

Arms	Assigned Interventions
	Procedure/Surgery: Transjugular intrahepatic portosystemic shunt (TIPS) Transjugular intrahepatic portosystemic shunt (TIPS)
Experimental: B PTFE Covered Stents	Device: PTFE Covered Stents: Fluency® (Bard), Advanta V12® (Atrium) and Viatorr® (Gore) Vascular Stents Procedure/Surgery: Transjugular intrahepatic portosystemic shunt (TIPS) Transjugular intrahepatic portosystemic shunt (TIPS)

Outcome Measures

Primary Outcome Measure:

1. TIPS permeability rate
   [Time Frame: one year] [Safety Issue: Yes]
2. Cost of the TIPS and patient care according to the type of stent used brought back to an indicator of effectiveness
   [Time Frame: one year] [Safety Issue: Yes]

Secondary Outcome Measure:

3. Tolerance criteria : frequency of early complications like early thrombosis - probability of hepatic encephalopathy occurrence and gravity
   [Time Frame: one year] [Safety Issue: Yes]
4. Quality of life
   [Time Frame: one year] [Safety Issue: Yes]
5. Effectiveness criteria : survival rate - recurrence rate of the symptoms having justified the TIPS - various types of dysfunction
   [Time Frame: one year] [Safety Issue: Yes]
6. Doppler : performance evaluation of Doppler for the diagnosis of dysfunction
   [Time Frame: one year] [Safety Issue: Yes]

Eligibility

Minimum Age: 18 Years

Maximum Age: 75 Years

Gender: Both

Accepts Healthy Volunteers?: No

Criteria: Inclusion Criteria:

- Presence of a cirrhosis as documented by previous liverbiopsy or typical clinical signs
- Indication validated of the TIPS (Bavéno IV), except not-controlled acute hemorrhagic :
  - Recurrent variceal bleeding after failure of the usual pharmacological and endoscopic methods
  - Refractory or recurrent ascites or difficult to treat
  - Refractory Hydrothorax

Exclusion Criteria:

- Non cirrhotic HTP
- CHILD C ≥12
- Complete portal vein thrombosis

- Usual contra-indication for TIPS :
  - Known or suspected Hepatocarcinoma by increase of the alpha-foetoprotein >100 UI/mL associated with the presence of at least one hepatic nodule
  - Cardiac insufficiency defined by a ventricular fraction of ejection < 40% with the echocardiography preliminary to the procedure
  - Pulmonary arterial hypertension (PAP > 40 mmHg)
  - Hepatic polycystosis
  - Intra-hepatic bile ducts dilatation,
  - Spontaneous clinical recurrent hepatic encephalopathy

Contacts/Locations

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Links:

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