Protocol Registration Receipt
12/01/2011

Portal Vein Thrombosis Relevance on Liver Cirrhosis: Italian Venous Thrombotic Events Registry (PRO-LIVER)

This study is currently recruiting participants.
Verified by Francesco Violi, University of Roma La Sapienza, December 2011

Sponsor:	University of Roma La Sapienza
Collaborators:	
Information provided by (Responsible Party):	Francesco Violi, University of Roma La Sapienza
ClinicalTrials.gov Identifier:	NCT01470547

Purpose

The portal vein thrombosis (PVT) can complicate medical conditions like liver cirrhosis (LC), neoplasms, myeloproliferative diseases, thrombophilic genotypes, infections, inflammatory diseases, trauma and surgery. LC is an important predisposing disease and is responsible for about 20% of all cases. However, data regarding the PVT in cirrhosis are insufficient.

Early studies have shown that, in absence of hepatocellular carcinoma (HCC), the PVT can occur in approximately 10% of cirrhotic patients.

Most of studies are in support of a prevalence between 5 and 20% of patients with LC. A study in transplant recipients, has documented that in variable etiology cirrhosis, the PVT was present in 15.7% of patients, a higher percentage was found in patients with liver cancer (34.8%), while primary biliary cirrhosis (7.9%) and sclerosing cholangitis (3.6%) are less frequently complicated by PVT.

The PVT development is due to stagnation in the portal circulation, but alterations in the sense of inherited or acquired pro-coagulant may favor its appearance.

The causal association of PVT with bleeding and bowel infarction suggests that the PVT may reduce survival in cirrhosis, but data are lacking on this issue. It is also not known whether asymptomatic patients with PVT have a

different survival compared to cirrhotic patients without PVT. Further studies should be conducted to clarify this issue.

Likewise, prospective studies are needed to better identify risk factors predisposing to PVT in LC patients as well as to clarify the relationship between cirrhosis severity and PVT. The impact of PVT on the natural history of cirrhosis is an issue today still debated.

The PVT not only favour life-threatening complications (gastrointestinal bleeding and mesenteric thrombosis) but could also contribute to a deterioration of liver function by reducing portal flow. Obtaining such information would be of crucial importance considering that the evidence of increased mortality related to PVT in liver cirrhosis may indicate the need for randomized controlled trials to clarify the potential effectiveness of anticoagulant therapy to improve the survival.

To this purpose it's proposed to establish an Italian register of patients with cirrhosis. In the second phase of the project is planned a 2-years follow-up program in order to assess whether the PVT be an additional risk factor for mortality or deterioration of the natural history in patients with cirrhosis.

Condition
Liver Cirrhosis Portal Vein Thrombosis

Study Type: Observational
Study Design: Cohort, Prospective
Official Title: Portal Vein Thrombosis Relevance On Liver Cirrhosis: Italian Venous Thrombotic Events Registry

Further study details as provided by Francesco Violi, University of Roma La Sapienza:

Biospecimen Retention: Samples Without DNA

Plasma and serum samples

Primary Outcome Measure:

- PVT Prevalence [Time Frame: 1 year] [Designated as safety issue: No]

  To estimate the prevalence of PVT evaluated by US with power-doppler in a cohort of patients with liver cirrhosis of any etiology and severity.

Secondary Outcome Measures:

- Thrombotic Events [Time Frame: 2 years] [Designated as safety issue: No]

  Occurrence of thrombotic complications (deep vein and portal vein thrombosis)

- Mortality [Time Frame: 2 Years] [Designated as safety issue: No]

  Overall mortality in a cohort of cirrhotic patients

- Cirrhosis Complications [Time Frame: 2 Years] [Designated as safety issue: No]

  Occurrence of digestive or other bleeding complications; Occurence of other cirrhosis-related complications (previous refractory ascites or hepatic encephalopathy; onset or progression of oesophageal varices, ascites or refractory ascites, jaundice, onset of liver cancer, infections, spontaneous bacterial peritonitis, onset of hepato-renal or hepato-pulmonary syndrome)

Estimated Enrollment: 1100
Study Start Date: December 2011
Estimated Study Completion Date: December 2014
Estimated Primary Completion Date: December 2012

Number of arms: 1

Study Design: Prospective Longitudinal Study.

The investigators planned to assess at baseline and at scheduled follow up visits:

- Medical history collection with thrombosis risk factors evaluation;
- Clinical parameters collection;
- Upper abdomen ultrasound and portal district echo color doppler to evaluate the presence of PVT;
- Esophagogastroduodenoscopy;
- Routine blood samples collection with plasma and urine storage;

At every follow up visit will be evaluated all relevant clinical events and will be recorded all treatments received during the follow-up period.

Sample Size: The investigators plan to include in the study n = 1100 patients. The sample size was calculated assuming an expected prevalence of 18% at time zero, and in order to obtain a confidence interval 95% to prevail at time zero whose distance from the edge is less than or equal to 3%.

Eligibility

Liver cirrhosis patients

Sampling Method: Probability Sample
Ages Eligible for Study: 18 Years to 90 Years
Genders Eligible for Study: Both

Inclusion Criteria:

- Cirrhosis of any etiology and severity (including HCC)
- Signed Written Informed Consent

Exclusion Criteria:

- Extrahepatic neoplasms

Contacts and Locations

Contacts

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Locations

Italy

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Investigators

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More Information

Società Italiana di Medicina Interna

http://www.simi.it

Responsible Party:	Francesco Violi, Clinical Professor, University of Roma La Sapienza
Study ID Numbers:	SIMI PRO-LIVER
Health Authority:	Italy: Ethics Committee