Gastrointestinal Ischemia in Acute and Chronic Portal Vein Thrombosis

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To evaluate the prevalence of gastrointestinal ischemia in patients with acute and chronic non-cirrhotic, non-malignant PVT.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Gastrointestinal vascular conditions
Study type	Observational non invasive

Summary

ID

NL-OMON39226

Source
ToetsingOnline

Brief title
Ischemia and Portal Vein Thrombosis

Condition

- Gastrointestinal vascular conditions
- Hepatic and hepatobiliary disorders
- Embolism and thrombosis

Synonym
portal vein obstruction, thrombosis of the portal vein

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: gastrointestinal ischemia, portal vein thrombosis, venous thrombosis

Outcome measures

Primary outcome

The prevalence of gastrointestinal ischemia in patients with non-cirrhotic, non-malignant PVT.

Secondary outcome

- Evaluation of cardiovascular risk factors
- Evaluation of small bowel function using a sugar-absorption test (SAT)
- Comparison of visible light spectroscopy with findings at duplex ultrasound examination
- Prevalence of gastrointestinal ischemia in patients with acute and chronic PVT
- Prevalence of gastrointestinal ischemia in patients with an extended thrombosis of the portal vein (i.e. additional thrombosis of the superior mesenteric vein), as detected by duplex ultrasound
- Relationship between diagnosis of gastrointestinal ischemia and symptoms
- Comparison of mucosal saturation measurements using VLS between patients with PVT and patients with liver cirrhosis and portal hypertension with patent mesentery arteries and veins

Study description

Background summary

Thrombosis of the portal vein, in the absence of cirrhosis or malignancy, is a rare clinical entity. Venous congestion resulting from a thrombotic obstruction

of the portal vein can potentially lead to gastrointestinal ischemia. Due to the rarity of this disorder, no controlled studies have been performed and therefore it is unknown what the true frequency is of gastrointestinal ischemia in patients with portal vein thrombosis. The major risk associated with gastrointestinal ischemia is development of intestinal infarction. Infarction and subsequent necrosis of (part of) the gastrointestinal tract is a serious complication with a high risk of morbidity and mortality. Furthermore, long-standing ischemia of the gastrointestinal tract can lead to a number of complaints such as post-prandial abdominal pain, decreased apetite and weight loss. More insight into the prevalence and clinical presentation of gastrointestinal ischemia in patients with portal vein thrombosis can contribute to an improvement of the treatment and care of these patients.
Since many patients with PVT have portal hypertension, we cannot assume that decreased mucosal saturation measurements are only attributed to the presence and extent of the portal and mesentery vein thrombosis but also to the presence of portal hypertension. This could be a possible confounding factor for the mucosal saturation measurements.
To determine whether the mucosal saturation measurements in patients with PVT are only affected by the presence of presence and extent of the portal and mesentery vein thrombosis and not portal hypertension, a comparison in mucosal saturation measurements is needed between patient with PVT and a control group consisting of patients with liver cirrhosis and evident portal hypertension.
Portal hypertension is defined as: the presence of varices and/or splenomegaly and/or ascites and/or hepatic hydrothorax and/or increased hepatic venous pressure gradient (>12 mm Hg) AND in the absemce of an intrahepatic shunting stent (i.e. TIPS).

Study objective

To evaluate the prevalence of gastrointestinal ischemia in patients with acute and chronic non-cirrhotic, non-malignant PVT.

Study design

A single-center cohort study conducted by the Department of Gastroenterology and Hepatology of the Erasmus MC, University Medical Center Rotterdam. All patients diagnosed with or referred to this center for evaluation of acute or chronic non-cirrhotic, non-malignant PVT are asked to participate in the study.

Study burden and risks

Inclusion in this study does not result in additional risks for the participants because almost all investigations will take place during scheduled interventions. Visible light spectroscopy will take place during a regular diagnostic gastroscopy and this test will lengthen the procedure by no more than two minutes. Abdominal ultrasound is not associated with any risks for the

participant, due to additional visualisation of the main abdominal arteries for this study the ultrasound may take a few minutes longer (10 minutes longer at most). To perform a sugar absorption test, urine samples of the patient need to be collected after ingestion of a sugar-containing drink for a period of five hours. During this time period the patient will have to remain in the hospital. Apart from the time-burden associated with this test, there are no risks involved. As part of the study a single blood sample is drawn by venapuncture from all patients. During every venapuncture there is a minimal risk of pain, swelling or infection around the puncture-site.

Control group
Patients with liver cirrhosis admitted for screening for liver transplantation, will undergo the standard work-up for screening. This work-up includes radiological imaging by abdominal duplex ultrasound and CT scanning of the liver and the liver vasculature and also an upper gastrointestinal endoscopy to assess and grade gastro-esophageal varices. Therefore no additional diagnostic procedures are needed to assess presence of thrombosis of the mesenterial vasculature or to perform the mucosal saturation measurements. For these patients, no additional blood samples need to be collected for determination of cardiovascular risk factors, as this is already part of standard work-up for screening for liver transplantation. Due to the highly unlikely chance of small bowel dysfunction in these patients, the sugar absorption test will not be performed.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- Unambiguous evidence of complete thrombosis of the main portal vein (endoluminal material and absence of flow or presence of cavernous transformation), as detected by proper imaging techniques (duplex ultrasound, computerised tomography (CT), magnetic resonance imaging (MRI) or venography).
- Date of diagnosis after 01-01-2000
- Age >18 years
- Signed informed consent;Controlgroup:
- >18 years
- Signed informed consent
- Patients with liver corrhosis and portal hypertension
- Patent mesentery arteries and veins

Exclusion criteria

- Liver cirrhosis
- Malignancy
- No informed consent
- Pregnant or lactating women;Controlgroup:
- <18 years
- No informed consent
- Stenosis/thrombosis of the mesentery arteries and veins
- Presence of an open intrahepatic shunting stent (i.e. TIPS)

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-02-2009
Enrollment:	60
Type:	Actual

Ethics review

Approved WMO Date:	18-12-2008
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	13-04-2010
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	21-10-2013
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL24909.078.08