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Gastrointestinal ischemia in patients with portal vein thrombosis

Submission date	Recruitment status	[ ] Prospectively registered
16/02/2015	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
19/02/2015	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
23/04/2015	Circulatory System	[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Portal vein thrombosis (PVT) refers to a blockage of the portal vein (the blood vessel supplying blood to the liver from the intestines) by a blood clot. It often leads to portal hypertension, where the blood pressure in the portal vein is higher than it should be. PVT can occur suddenly (acute) or chronic (which results from acute PVT that does not respond to treatment). Gastrointestinal ischemia, caused by a fall in the blood flow to the intestines, is a feared complication of PVT. It can result in intestinal infarction, a life-threatening complication where parts of the bowel start to die due to lack of a blood supply (and therefore oxygen) that often requires immediate surgery. Treatment of acute PVT therefore aims at vascular recanalization (reopening blocked blood vessels), to prevent portal hypertension and gastrointestinal ischemia. Due to the rarity of the disease and lack of adequate diagnostic tools in the past, most data on gastrointestinal ischemia in patients with PVT stem from studies using past clinical records from selected patient populations. With the development of minimally invasive techniques, such as visible light spectroscopy (VLS), the ability to diagnose gastrointestinal ischemia has greatly improved. Therefore, we studied patients with PVT using VLS, radiological examination, and questionnaires. The aim of this study is to test for the presence, clinical presentation and characteristics of gastrointestinal ischemia in patients with PVT.

Who can participate?
Patients over 18 with PVT not caused by cirrhosis of the liver or cancer

What does the study involve?
For each participant in the study, clinical symptoms of gastrointestinal ischemia are assessed by a structured questionnaire, VLS measurements and radiological evaluation of the mesenteric arteries (arteries supplying blood to the intestines)

What are the possible benefits and risks of participating?
Patients who are willing to participate in the study will be fully informed of the reason of the study, the extent and duration of their co-operation, the voluntary nature of their involvement and their freedom to drop out at any time without reason. They will be told that they will not

get any personal medical benefits from participating. There are no risks involved in participating this study. Patients with PVT have endoscopy on regular basis and VLS is a painless method to measure the oxygen saturation.

Where is the study run from?
Erasmus MC University Medical Center (Netherlands)

When is the study starting and how long is it expected to run for?
December 2008 to January 2015

Who is funding the study?
The Foundation for Liver and Gastrointestinal Research (SLO) (Netherlands)

Who is the main contact?
Dr Jihan Harki

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
NL24909.078.08

Study information

Scientific Title
Gastrointestinal ischemia in patients with portal vein thrombosis: a prospective study

Acronym

GASTROINTESTINAL ISCHEMIA IN PVT

Study objectives
The objective of this study is to assess the presence, clinical presentation and characteristics of gastrointestinal ischemia in patients with PVT.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Institutional Review Board of the Erasmus MC University Medical Center Rotterdam (Netherlands), ref: MEC 2008-375.
2. Central Committee on Research Involving Human Subjects (CCMO) (Netherlands), ref: NL24909.078.08.

Study design
Patients with non-cirrhotic, non-malignant PVT were studied in this single-center prospective cohort study in a tertiary care center.

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Diagnostic

Participant information sheet

Health condition(s) or problem(s) studied
Portal vein thrombosis (PVT)

Interventions
Clinical symptoms of gastrointestinal ischemia were assessed by a structured questionnaire, VLS measurements and radiological evaluation of the mesenteric arteries

Intervention Type
Device

Primary outcome measure
1. Symptoms of gastrointestinal ischemia in patients with PVT
2. Mucosal saturation measurements in the gastrointestinal tract in patients with PVT

Secondary outcome measures
Factors related to gastrointestinal ischemia in patients with PVT

Overall study start date

08/12/2008

Completion date
01/01/2015

Eligibility

Key inclusion criteria
1. Patients with non-cirrhotic, non-malignant PVT. Acute and chronic PVT were defined according to Baveno V criteria as presence of PVT with or without portal cavernoma and portal hypertension.
2. Aged 18 years and over

Participant type(s)
Mixed

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
20

Key exclusion criteria
1. Patients < 18years
2. No informed consent
3. Patients with liver cirrhosis
4. Patients with malignancy
5. Pregnant or lactating women

Date of first enrolment
18/01/2009

Date of final enrolment
01/01/2015

Locations

Countries of recruitment
Netherlands

Study participating centre

Erasmus MC University Medical Center
's Gravendijkwal 230
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3015 CE

Sponsor information

Organisation
Erasmus MC University Medical Center

Sponsor details
's Gravendijkwal 230
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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/018906e22

Funder(s)

Funder type
Charity

Funder Name
The Foundation for Liver and Gastrointestinal Research (SLO) (Netherlands)

Results and Publications

Publication and dissemination plan

Intention to publish date
01/03/2015

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Available on request