Blood Platelet Function During and After Liver Resection; an observational study

Published: 11-11-2011
Last updated: 29-04-2024

We will examine the activation status of platelets, the content of platelet granules, and activation of de novo synthesis of mitogenic proteins during and after a partial liver resection in patients with a malign or benign tumor including distant...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Hepatobiliary neoplasms malignant and unspecified
Study type	Observational invasive

Summary

ID

NL-OMON39312

Source
ToetsingOnline

Brief title
Blood Platelet Function During and After Liver Resection

Condition

- Hepatobiliary neoplasms malignant and unspecified

Synonym
liver tumors, malign or benign liver tumor(s) including distant metastasis to the liver

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: NWO in het kader van Mozaiëk subsidie

Intervention

Keyword: blood platelets, liver resection

Outcome measures

Primary outcome

In this study we will examine at different timepoints during or after a liver

resection or a PPPD:

a) the activation status of platelets

b) platelet activatability

c) the content of platelet granules, and

d)t he activation of de novo synthesis of mitogenic proteins.

Secondary outcome

N/A

Study description

Background summary

De liver has a unique capacity to regenerate following surgical resection of part of the liver. Bloodplatelets have been shown to play a crucial role in liver regeneration after a liver resection in rodents. Also human studies suggest an important role of platelets in liver regeneration after resection. The precise meolecular mechanisms involved in platelet-mediated regeneration are thusfar unclear. It appears plausible that growth factors that are stored in platelet storage granules play a role, but it is unclear when and how these growth factors are released during the process of regeneration. Platelet activation is required for release of storage granule content, but it is unknown if and when platelets are activated during the course of regeneration. Recent studies have also shown that grwoth factors can be synthesized de novo by platelets, but it is unknown whether this process is activated in vivo following a liver resection.

Study objective

We will examine the activation status of platelets, the content of platelet granules, and activation of de novo synthesis of mitogenic proteins during and after a partial liver resection in patients with a malign or benign tumor including distant metastasis to the liver. We aim to dissect the contribution of liver regeneration and of the surgical procedure itself on the platelet activation status, the content of platelet granules, and the amount of unspliced versus spliced mRNA for the various growth factors. Our control group consists of patients who undergo a pylorus preserving pancreaticoduodenectomy (PPPD) for pancreatic head cancer.

Study design

Observational

Study burden and risks

In this study we will draw a blood sample at different time points during and after surgery. This risk of the blood draw is a local hematoma. The circulating blood volume will not be significantly affected by the blood draw. Intraoperatively we will take a blood sample directly from the portal vein and directly from the hepatic artery. This risk associated with these blood draws is very small and will not have any influence on operation procedure and outcome. Earlier studies have shown that our HPB team is able to draw blood from these vessels safely. Worst case scenario is a bleeding, which will be arrested by a single suture.

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

Sutdy group: (extended) right hemi-hepatectomy for a malign or benign tumor including distant metastasis the liver
For the control group: pylorus preserving pancreaticoduodenectomy for pancreas head cancer.

Exclusion criteria

1) age: patients younger than 18 and older than 65 years of age;
2) patients who use (selective)serotonin reuptake inhibitors (SSRI);
3) patients with arterial thrombosis in their medical history;
4) patients who use anticoagulants such as vitamin K antagonists, aspirin, and plavix;
5) patients with liver cirrhosis.

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	13-01-2012
Enrollment:	30
Type:	Actual

Ethics review

Approved WMO Date:	11-11-2011
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	16-07-2013
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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	NL36835.042.11