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

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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**

#### **Public**

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#### **Scientific**

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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

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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