# Functional and biochemical assessment of liver regeneration after major hepatectomy

Published: 19-01-2018
Last updated: 15-05-2024

Quantification of postoperative change of liver function (measured with hepatobiliary scintigraphy). This change will be correlated with liver regeneration by measuring circulating regeneration-related biomarkers at different timepoints...

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

## Summary

### ID

NL-OMON46514

**Source**
ToetsingOnline

**Brief title**
FLASH study

### Condition

- Hepatobiliary neoplasms malignant and unspecified

**Synonym**
bile duct tumor, colorectal liver metastsasis, Liver tumor

**Research involving**
Human

### Sponsors and support

**Primary sponsor:** Chirurgie
**Source(s) of monetary or material Support:** Ministerie van OC&W

## Intervention

**Keyword:** Hepatobiliary scintigraphy, Liver regeneration, Liver stiffness measurement, Liver surgery

## Outcome measures

### Primary outcome

Correlations between the changes in liver function (as measured with

hepatobiliary scintigraphy) at day of admission versus postoperative day 5 and

the concomitant changes in circulating regeneration biomarkers

### Secondary outcome

Variability of liver function whithin a patient.

Correlation between postoperative changes in liver stiffness and changes in

liver function (as measured with hepatobiliary scintigraphy) at day of

admission versus postoperative day 5

# Study description

### Background summary

Posthepatectomy liver failure (PHLF) is the most severe complication that can occur after major liver resection with an incidence between 7% in patients with healthy parenchyma and reaching 30% in patients with liver cirrhosis. The current management is mostly supportive and PHLF has a mortality rate of over 80%.
After hepatectomy, the remaining hepatocytes undergo regeneration which is a crucial step for the liver to uphold its function. When this is insufficient, due to decreased functional mass, PHLF develops.
In order to minimize the risk of PHLF, pre-operative assessment of liver function is undertaken with the use of liver function test. Hepatobiliary scintigraphy (HBS) is a validated quantitative dynamic liver function test that is able to calculate the global and regional liver function.
Another tool to assess the quality of liver parenchyma is liver stiffness measurement (LSM).Transient elastography (TE) is a non-invasive ultrasound-based method that measure tissue stiffness. Liver elasticity is

correlated with grade of fibrosis, parenchymal inflammation and bile outflow obstruction.
So far, no studies have been conducted that assess the postoperative change in liver function in relation to liver regeneration. Evaluating the role of biomarkers in postoperative liver function can provide new insights in the regeneration physiology, potentially leading to new monitoring tools or therapeutic strategies aimed at preventing or treating PHLF. Furthermore, the change in liver stiffness after liver resection and it*s correlation with regeneration, inflammation and other complications remains unanswered. Perioperative measurements of liver stiffness could provide useful means for assessing the physiology of liver regeneration and might provide an easy accessible, cheap and non-invasive bed-side monitoring tool for postoperative patients.

### Study objective

Quantification of postoperative change of liver function (measured with hepatobiliary scintigraphy). This change will be correlated with liver regeneration by measuring circulating regeneration-related biomarkers at different timepoints postoperatively. Furthermore, to correlate postoperative tissue elasticity with these biomarkers and change in liver function.

### Study design

Prospective observational pilot study

### Study burden and risks

Participating in this study leads to no advantage for the individual patient.
The burden for the patient is three additional HBS-scans outside of standard practice, this scan takes 30-45 minutes and has a radiation burden ranging between 5.1-6.8 mSv per scan. HBS is safe and part of standard work-up and entails minimal risk to the patient. The time burden is 30-45 minutes per scan. Furthermore, three LSM will be performed at bedside or outpatient clinic, this has no radiation burden, is painless and non-invasive. The time investment is approximately 5-10 minutes per time. Lastly, blood drawings consist of 3 extra tubes (in total 15.7 mL) per time-point. There will be no extra blood drawing moments outside of standard practice. No additional site visits outside of standard practice are required for this study.

## Contacts

**Public**
Selecteer

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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

Major liver resection (3 or more Couinaud segments)
Written informed consent
>= 18 years old

## Exclusion criteria

Serum bilirubine > 50 µmol/L
'Two-stage' procedures
ALPPS procedure
Allergy for mebrofenin
Pregnant

# Study design

## Design

**Study type:** Observational invasive

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| Masking: | Open (masking not used) |
| Control: | Uncontrolled |
| Primary purpose: | Diagnostic |

## Recruitment

NL

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|---|---|
| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 15-02-2018 |
| Enrollment: | 33 |
| Type: | Actual |

# Ethics review

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| Approved WMO Date: | 19-01-2018 |
| Application type: | First submission |
| Review commission: | METC Amsterdam UMC |
| Approved WMO Date: | 22-05-2018 |
| Application type: | Amendment |
| Review commission: | METC Amsterdam UMC |
| Approved WMO Date: | 27-08-2018 |
| Application type: | Amendment |
| Review commission: | METC Amsterdam UMC |

# Study registrations

## Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 22009
Source: NTR
Title:

## In other registers

| Register | ID |
|---|---|
| CCMO | NL63868.018.17 |
| OMON | NL-OMON22009 |