ReSPECT study; Assessment of the Future Remnant Liver before partial liver resection by 99mTc-mebrofenin SPECT volumetrie

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

Summary

ID

NL-OMON29787

Source
ToetsingOnline

Brief title
ReSPECT study

Condition

- Hepatobiliary neoplasms malignant and unspecified
- Hepatobiliary therapeutic procedures

Synonym
liver cancer, liver tumour

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: MLDS subsidie aanvraag ingediend.

Intervention

Keyword: liver function, liver functional volume, liver resection, liver volume

Outcome measures

Primary outcome

liver volume

liver functional volume

liver function

Secondary outcome

not applicable

Study description

Background summary

Surgical resection is the most effective treatment for hepatic malignancies. Extended resections are performed more frequently. However, the risk of postoperative liver failure increases when too much liver is resected, particularly in patients with coexisting parenchymal liver diseases such as cirrhosis or steatosis. Preoperative evaluation of the function of the future remnant liver (FRL) is therefore crucial for deciding on the extent of resection. Current guidelines for safe resections are based on preoperatively determined FRL volume by CT. Safe resection can be performed if the FRL volume exceeds 30-40% of the total liver volume. In patients with coexisting parenchymal liver disease, CT-volumetry may not represent actual liver function. Furthermore, the importance of preoperative assessment of hepatic function has increased because of recent availability of preoperative interventions to increase FRL function by portal vein embolization (PVE). After PVE, it is important to quantify hypertrophy and function of the non-embolized liver lobes. However, few methods are available to measure regional liver function. After partial liver resection, the liver has the unique ability to regenerate. However the capacity of the liver to regenerate is influenced by multiple

factors. Therefore it is important to evaluate the regeneration process after a partial hepatectomy.
Hepatobiliary scintigraphy (HBS) using 99mTc-mebrofenin is a non-invasive, quantitative method for the evaluation of total and regional liver function. To enable the assessment of functional volumes and improve assessment of liver function on the segmental level, 3-dimentional 99mTc-mebrofenin Single Photon Emission Computed Tomography (SPECT) has recently been introduced.

Study objective

The aim of this study is to assess the clinical value of 99mTc-mebrofenin SPECT for the measurement of liver functional volume in patients planned for liver resection, in comparison to CT-volumetry. Furthermore, the significance of liver volume in comparison to liver function, measured with HBS and SPECT is assessed.

Study design

Patients are selected for PVE when the FRL volume is less than 30% of total liver volume in livers with normal parenchyma, or less than 40% in livers with compromised liver parenchyma.
Patients within the safely limits will be resected without PVE. Based on the histopathological examination of the resection specimen, patients will be divided retrospectively in patients with normal livers and compromised livers.
Preoperative workup includes the following parmeters: liver volume measured by CT volumetry, liver functional volume measured by SPECT, liver function measured by HBS and ICG clearance. Total liver volume and function, as well as FRL function and volume is measured. After the resection, SPECT and HBS are performed to measure actual remnant liver function and functional volume. The preoperative estimated FRL function is compared with actual postoperative function.
In the PVE group, a CT scan, HBS and SPECT are performed three weeks after resection to measure the hypertrophy of the FRL. Three months after the operation, a CT scan, HBS and SPECT are performed for the assessment of regeneration.

Study burden and risks

Patients included in the study receive additional radiation. The additional radiation is evaluated by the Radiation Committee. Intravenous injections required for the HBS, and blood sampling needed for the ICG clearance tests, cause some additional discomfort. There is a small risk of an allergic reaction after the injection of ICG.

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

All patients above 18 years old planned for a resection of two or more segments for benign or malignant tumours of the liver.

Exclusion criteria

pregnancy
traumatic liver injury
patients below 18 years old

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-09-2006
Enrollment:	80
Type:	Anticipated

Ethics review

Approved WMO

Application type:	First submission
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

No registrations found.

In other registers

Register	ID
CCMO	NL13705.018.06