Assessment of liver function with Dynamic Contrast-Enhanced MRI in patients scheduled for liver resection - a pilot study.

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To compare DCE-MRI of the liver with the liver-specific contrast agent Gd-EOB-DTPA with 99mTC-HBS in patients scheduled for liver resection in estimation of (regional) liver function.

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

Summary

ID

NL-OMON46928

Source
ToetsingOnline

Brief title
DCE-MRI vs. 99m-Tc HBS

Condition

- Hepatobiliary neoplasms malignant and unspecified

Synonym
Liver cancer, liver metastasis

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: DCE-MRI, Hepatobiliary scintigraphy, Liver function, Liver resection

Outcome measures

Primary outcome

* DCE-MRI: maximum enhancement, time to peak, slope of enhancement, wash-out rate

* Quantitative T1 mapping: *T1

* 99mTc-HBS (performed as part of clinical work-up): liver uptake function

Secondary outcome

* Liver fat percentages (MR fat mapping)

* Liver microperfusion (IVIM)

* Histology results of the microscopic examination of the resected liver:

* Degree of fibrosis and steatosis

* Histology results of the microscopic examination of the liver biopsy of the future remnant liver:

* Degree of fibrosis and steatosis

Study description

Background summary

Surgical resection remains the most effective treatment in patients with hepatic malignancies. In the last decades the number of extended surgical resections has increased. Extended resection can result in a small postoperative future remnant liver (FRL) leading to postoperative liver failure and mortality. Therefore, preoperative assessment of FRL is of great importance. Computed tomography (CT) volumetry is considered the gold standard in the preoperative assessment of patients scheduled for major liver resection. However, FRL volume is not per se representative for FRL function, especially

in patients with a compromised (i.e. steatosis, fibrosis, cholestasis) liver parenchyma. Liver function can be divided in uptake, biotransformation, synthesis and excretion. Clinically used serum liver function tests provide an indirect evidence of only one of these processes and all of them lack the possibility to assess regional liver function. 99mTc labelled mebrofenin hepatobiliary scintigraphy with single emission proton CT (99mTc-HBS with SPECT) has been validated as a tool to assess total and regional liver function and is part of standard preoperative work-up at our centre. Nonetheless, 99mTc-HBS has disadvantages as well: radiation burden for the patient and inferior quality of the SPECT images for use in the diagnostic process.

In the last decades the use of Gd-EOB-DTPA-enhanced MRI has been introduced as an imaging technique in the diagnostic work-up in patients suspected of liver malignancies, providing high sensitivity for the detection of liver lesions. The pharmacokinetic properties of Gd-EOB-DTPA are similar to those of mebrofenin used in 99mTc-HBS. Applying the dynamic contrast enhanced-MRI (DCE-MRI) technique with Gd-EOB-DTPA allows assessment of its pharmacokinetic behaviour in liver parenchyma including the FRL, allowing a functional evaluation.

In this pilot study we will test this hypothesis by comparing DCE-MRI with Gd-EOB-DTPA with 99mTc-HBS. Furthermore we plan to measure the effect of Gd-EOB-DTPA on the intrinsic T1 relaxation times. This will allow the extraction of absolute concentrations of Gd-EOB-DTPA in the liver with a high resolution. Finally, liver fibrosis, steatosis and microperfusion can now reliably be assessed with MRI, allowing a regional comparison of liver function with liver fibrosis, steatosis and microperfusion levels. As we will obtain histological results of both the resected liver tissue as well as the future remnant liver (peroperative liver biopsy), these MRI parameter will be correlected with histological characteristics as well.

Study objective

To compare DCE-MRI of the liver with the liver-specific contrast agent Gd-EOB-DTPA with 99mTC-HBS in patients scheduled for liver resection in estimation of (regional) liver function.

Study design

Single-centre observational study

Study burden and risks

Participating in this study leads to no immediate advantage for the individual participant. However, it is important to evaluate whether DCE-MRI of the liver using Gd-EOB-DTPA can be used to derive information on total and future remnant

liver parenchyma function similar to that which the 99mTc-HBS can provide but with better spatial resolution. In the future, this may lead to better stratification of patients scheduled for possible liver resection into those who are eligible, those who may require portal vein embolization and those who are not eligible for resection. If this can be achieved, patients with focal liver disease may then benefit considerably.

Additionally, knowledge of individual liver and steatosis (measured with MRI-fatmaps) can be beneficial for future follow-up.

The burden for subjects consists of one extra visit to the hospital (if the sessions can not be scheduled on the same day) in which one extra MRI examination is performed which will take approximately 50 minutes in the MR-scanner. Subjects are asked to fast for at least 4 hours before the MR examination. Routine dosages of contrast agent (Gd-EOB-DTPA) are administered to subjects. Adverse reactions to contrast agent administration are rare. 10 mL of blood will be drawn from each subject prior to MRI examination at the placement of the I.V. line. In the unlikely case of unexpected findings on the MR images (e.g. hitherto undiagnosed liver lesions), the consulting surgeon will be notified as this may have consequences for the treatment strategy.

The burden for subjects additionally consists of a perioperative liver biopsy of the future remnant liver (circa 1 cm3), which is considered a safe procedure, as any bleeding that could occur at the biopsy site can be inspected visually by the surgeon and stemmed if necessary.

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

* Patients diagnosed with one or more liver lesions who are scheduled for 99mTc-HBS
* Visit 1 scheduled within preferably 7 but at most 14 days before or after 99mTc-HBS (with at least 4 hours between visits if scheduled on the same day)
* Age *18 years
* Signed informed consent obtained prior to any study-specific procedure

Exclusion criteria

* General contraindications for MRI (such as pregnancy and claustrophobia)
* Chronic renal insufficiency or eGFR < 30 ml/min/1.73 m2
* Known or family history of congenital prolonged QT-syndrome
* Prior history of arrhythmia after the use of cardiac repolarisation time prolonging drugs
* Prior history of allergic reaction to gadolinium-containing compounds
* Prior history of asthma bronchiale
* Prior history allergic conditions

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled

Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-12-2014
Enrollment:	20
Type:	Actual

Ethics review

Approved WMO Date:	11-09-2013
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	13-05-2014
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	17-07-2015
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	03-05-2018
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

No registrations found.

In other registers

Register	ID
CCMO	NL45755.018.13