Preoperative functional liver assesement with primovist enhanced MRI for patients with suspected resectable perihilar cholangiocarcinoma: a proof-of-concept pilot study

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To assess whether MRI Primovist could replace 99mTc-mebrofenin HBS as a preoperative functional liver assessment in addition to CT-volumetry in predicting PHLF in patients with resectable pCCA who require a major liver resection.

Ethical review	Approved WMO
Status	Will not start
Health condition type	Bile duct disorders
Study type	Interventional

Summary

ID

NL-OMON52335

Source
ToetsingOnline

Brief title
CAMPER study

Condition

- Bile duct disorders

Synonym
bile duct cancer, Biliary tract cancer

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Extended hemihepatectomy, Hemihepatecomy, MRI-Primovist, Perihilar cholangiocarcinoma, Portal vein embolization

Outcome measures

Primary outcome

• To assess whether MRI Primovist could replace 99mTc-mebrefenin HBS as a preoperative functional liver assessment in addition to CT-volumetry in predicting PHLF in patients with resectable pCCA who require a major liver resection.

Secondary outcome

• Define cut-off values of FLR for safe liver resection based on combined MRI-based functional and CT-based volumetric and functional (99mTc-mebrefenin HBS) measurements.

• Determine 90-day mortality.

• Occurrence of liver failure grade B or C according to the ISGLS criteria.

• Major postoperative complications (Clavien-Dindo >=3).

For patients undergoing PVE:

• Change in Primovist-based function of the future liver remnant (FLR), before and after PVE.

• Comparison of change of Primovist-based function of the future FLR with change in volume on CT, before and after PVE.

• Major complications attributable to PVE (Clavien-Dindo >=3).

• Comparison of findings with MRI based extracellular volume (ECV) measurements of the spleen before and after PVE performed with post-processing tools.

• Prediction of volume and functional increase of the FLR, based on imaging findings before PVE (including local segmental residual bile obstruction after drainage, liver volumetry and Primovist-based function of the FLR).

Study description

Background summary

90-day mortality after (extended) hemihepatectomy for perihilar cholangiocarcinoma (pCCA) is more than 10% in most Western centers. The majority of patients die as a consequence of posthepatectomy liver failure (PHLF). Portal vein embolization (PVE) was introduced to preoperatively enhance the future liver remnant (i.e. the part of the liver that remains in the patient after a liver resection). Postoperative liver failure and mortality are reduced when PVE increases the size of the future liver remnant. However, liver volume does not necessarily correlate with liver function. Another risk factor for PHLF is impaired liver function. Primovist enhanced Magnetic Resonance Imaging (MRI) is a quantitative functional assessment of the liver and has shown potential in assessing the risk of PHLF after liver resection.

Study objective

To assess whether MRI Primovist could replace 99mTc-mebrofenin HBS as a preoperative functional liver assessment in addition to CT-volumetry in predicting PHLF in patients with resectable pCCA who require a major liver resection.

Study design

A single-center, prospective proof-of-concept pilot study at Erasmus MC, including a total of 40 patients that can be used for analysis. The expected inclusion period is 3-4 years. All patients will preoperatively undergo CT volumetric assessment and 99mTc-mebrofenin hepatobiliary scintigraphy (HBS) (both standard of care) and Primovist enhanced MRI. In case of PVE, these assessments will be performed before and after PVE.

Intervention

Primovist enhanced MRI.

Study burden and risks

The most common adverse events following Primovist enhanced MRI are transient and of mild to moderate intensity. They include nausea and headache (1.1%), feeling hot (0.8%), back pain (0.6%) and dizziness (0.5%).

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

- Suspected resectable pCCA (as determined by the multidisciplinary hepatobiliary team, with or without histopathological confirmation), requiring an (extended) hemihepatectomy.
- Age > 18 years.
- Total bilirubin below 50 micromol/L before MRI-Primovist.

Exclusion criteria

- Patients who are planned for extrahepatic bile duct resection only.

Patients with the following criteria are excluded to undergo Primovist enhanced MRI:
- Contra-indication for MRI or gadoxetate disodium.
- Patients with known chronic liver disease based on liver function measurements, imaging findings (fibroscan, elastography, or CT/MRI based signs of cirrhosis and portal hypertension), and proven underlying hepatitis B/C or chronic alcohol abusus.

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	40
Type:	Anticipated

Ethics review

Approved WMO

Date:	15-09-2022

Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL79047.078.22

Study results

Summary results
Trial never started