Validation of MRI with Primovist® for Differentiation of Hepatocellular Adenoma and Focal Nodular Hyperplasia

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Validation of MRI with Primovist® for differentiation of FNH and HCA.Do imaging and histological outcome correlate?Is it possible to use MRI with Primovist® (as gold standard) in the diagnostic work-up of FNH and HCA?

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

Summary

ID

NL-OMON31336

Source
ToetsingOnline

Brief title
Validation of MRI with Primovist®

Condition

- Hepatobiliary neoplasms malignant and unspecified
- Hepatic and biliary neoplasms benign

Synonym
benign livertumours

Research involving
Human

Sponsors and support

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

Intervention

Keyword: diagnostic approach, focal nodular hyperplasia, hepatocellular adenoma, Primovist

Outcome measures

Primary outcome

Outcome of imaging studies, especially the MRI will be compared with the

histological outcome.

A pronouncement can be made about the accuracy of MRI with Primovist® for the

differentiation of FNH and HCA.

Secondary outcome

Comparison of histological outcome of the liver biopsy and the resection

specimen

Study description

Background summary

Focal nodular hyperplasia (FNH) and hepatocellular adenoma (HCA) are benign liver tumours, which predominantly occur in young and middle-aged women. Differentiation between FNH and HCA based on imaging studies remains difficult, but is important because both tumours require different therapeutic management1. The natural course of FNH is in most patients asymptomatic and no cases of malignant transformation are known, therefore conservative management is justified. In contrast, HCA (especially with a diameter >5cm) is an indication for surgery because of the risk of malignant transformation and the risk of spontaneous rupture and haemorrhage2-6. The current gold standard for diagnosis of these tumours is histological assessment.
Aim of this study is to assess the accuracy of MRI with Primovist® for differentiation of FNH and HCA. In this end, diagnosis based on MRI imaging with use of Primovist® is compared to histological outcome (core biopsy and/or resection preparate).

Study objective

Validation of MRI with Primovist® for differentiation of FNH and HCA.

Do imaging and histological outcome correlate?
Is it possible to use MRI with Primovist® (as gold standard) in the diagnostic work-up of FNH and HCA?

Study design

Prospective study. Patients referred to our hospital on the suspicion of HCA and/or FNH > 2cm are included. All patients will undergo a four phase CT scan and an MRI scan with Primovist®. An ultrasound is performed and guided biopsy is taken for histological investigation. When resection is performed, the resected part of the liver is also investigated histologically. The multiphasic CT scan and MRI scan with Primovist® will be read prospectively and separately by two abdominal radiologists. Based on known characteristics of the tumors, a diagnosis will be obtained. Finally the radiological outcome will be compared with the histological outcome and the role of MRI with Primovist® in the diagnostic work-up of HCA and FNH will be assessed.

Study burden and risks

In this study a four phase CT scan, an MRI with Primovist® and an ultrasound with liver core biopsy (16-18 gauche) are performed. Imaging guided biopsy has greatly improved the diagnostic accuracy of percutaneous liver biopsy, with a low degree of risk to the patient7. Complications of the liver biopsy include bleeding (0,03-0,04%8), seeding metastasis in case of malignancy (no percentages known in this context, but in case of HCC this risk is <2%9).

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 over 18 years of age referred to our hospital with suspicion of FNH and/or HCA >2cm. Informed consent must be obtained.

Exclusion criteria

Patients under 18 years of age
Patients who are pregnant
Patients with hemorrhage due to a ruptured lesion
Patients who are claustrophobic (MRI scan)
Patients who have magnetic or radiofrequency sensitive implants (MRI scan)
Patients with extreme obesity (MRI scan and US)
Patients with suspicion of a malignant lesion in the liver
Patients with known coagulation disorders
Patients with known systemic allergy for iodinated contrast
Patients with serious renal insufficiency

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):	01-10-2007
Enrollment:	100
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	NL18806.018.07