PRIDE-study.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON24607

Source
Nationaal Trial Register

Brief title
N/A

Health condition

focal liver lesions

Sponsors and support

Primary sponsor: Dr. R. van Hillegersberg, Surgeon
Coordinating Investigator/Project leader/Principal Investigator:
University Medical Center Utrecht
Heidelberglaan 100, 3584 CX Utrecht,
The Netherlands
Source(s) of monetary or material Support: We receive a grant from Bayer Health Care

Intervention

Outcome measures

Primary outcome

To determine the diagnostic value of MR-Primovist and Respiratory Triggered DWI MRI for the detection and characterization of focal liver lesions.

Secondary outcome

1. Accuracy and agreement between MR-Gadovist and MR-Primovist for lesion detection and characterization on a per lesion basis;

2. Change in surgical strategy.

Study description

Background summary

Rationale:

To make an efficacy evaluation of Gadolineum Ethoxybenzyl (Gd-EOB) DTPA-enhanced MR-imaging (Gadoxetic acid, Primovist, Bayer Schering Pharma, Berlin) and Respiratory Triggered Diffusion Weighted Imaging (DWI) for the detection and characterization of focal liver lesions.

Objective:

Primary Objective:

To determine the diagnostic value of MR-Primovist and Respiratory Triggered DWI MRI for the detection and characterization of focal liver lesions.

Secondary Objectives:

To determine the agreement for lesion detection and characterization between MR-Gadovist and MR-Primovist on a per lesion basis.

To assess the effect of MR-Primovist findings (lesion type, size, localisation) on surgical management (resection procedure) of patients with resectable disease.

Study design:

This is a prospective cohort study.

Study population:

We will include a total of 230 consecutive patients who are internally referred to the Radiology Department of the University Medical Centre Utrecht for a MRI of the liver because (of suspicion) of focal liver lesions.
Each patient will receive two MRI's of the liver after inclusion in this study. Both MRI's are performed according to the standard liver protocol of the UMC Utrecht, with Gadovist contrast enhancement in one MRI, and Primovist enhancement in the other MRI.

Primary study parameters/outcome of the study:

Negative predictive value and positive predictive value for the detection and characterization of focal liver lesions on a per patient basis.

Secondary study parameters/outcome of the study:

Accuracy and agreement between MR-Gadovist and MR-Primovist for lesion detection and characterization on a per lesion basis. Change in surgical strategy.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness:

After inclusion, each patient will receive two liver MRI's: one MRI with Gadovist enhancement, one MRI with Primovist enhancement. Since all these patients were referred to the Radiology Department for a Gadovist enhanced MRI of the liver, only the Primovist enhanced MRI is associated with an extra burden. The Diffusion Weighted Imaging images do not increase any risk or burden. Apart from the MRI investigations, each patient will be called by the study coordinator one week and one month after the Primovist enhanced MRI, to determine if any (S)AE occurred during the study period.

Primovist is a registered contrast agent with no more side effects than Gadovist, therefore no more (serious) adverse effects or (serious) adverse reactions are expected to occur compared to the standard liver MRI with Gadovist. Bayer Schering Pharma has extensively tested Primovist for its safety within phase 1,2 and 3 studies1-4.
In 10.3% of patients receiving Primovist AE's are expected1,2. The most frequent AE's that occur are headache and nausea with an incidence of 1.1%, which is comparable to other Gadolineum contrast agents*. No other AE's show any incidence higher than 1.1%*. No deaths are reported in phase 2 and 3 studies due to the administration of Primovist2,*. SAE's were classified according to the ICH-GCP definition and included any event resulting in death, were life-threatening, required inpatient hospitalization/prolonged existing hospitalization or resulted in persistent significant disability/incapacity or a congenital birth defect. SAE's were seen in 3.3% of patients with AE's and in 0.3% (6/1755) of total population*.
No other investigations, time-consuming events, questionnaires or visits to the hospital are

necessary when participating in this study. Participation in this study will result in a close and thorough investigation of the patients' liver disease, although patients do not necessarily benefit from participation.

Study objective

To make an efficacy evaluation of Gadolineum Ethoxybenzyl (Gd-EOB) DTPA-enhanced MR-imaging (Gadoxetic acid, Primovist, Bayer Schering Pharma, Berlin) and Respiratory Triggered Diffusion Weighted Imaging (DWI) for the detection and characterization of focal liver lesions.

Study design

Each patient will receive two MRI's of the liver after inclusion in this study. Both MRI's are performed according to the standard liver protocol of the UMC Utrecht, with Gadovist contrast enhancement in one MRI, and Primovist enhancement in the other MRI. A maximum of 1 month is allowed between these 2 MRI scans.

Intervention

1. Primovist enhanced MRI;

2. Gadovist enhanced MRI.

Contacts

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Eligibility criteria

Inclusion criteria

1. Age > 18 years;

2. Suspicion of focal liver lesions, both benign and/or malignant:

Benign:

A. Haemangioma;

B. Focal Nodular Hyperplasia;

C. Adenoma;

D. Cyst.

Malignant:

A. Metastasis;

B. Hepatocellular Cacrinoma (HCC).

Exclusion criteria

1. Clinical query on liver MRI chart directed to other liver disease than focal liver lesions like liver cirrhosis, hepatitis, or liver abscess (these are no exclusion criteria when apparent as secondary disease to focal disease);

2. Previous liver surgery;

3. A pacemake;r

4. Administration of a liver specific contrast agent within 2 weeks prior to the first MRI with Primovist;

5. Claustrophobia;

6. Hypersensitivity to the active substances or any of the recipients of Gd-EOB-DTPA contrast:

A. Previous reaction to contrast media;

B. History of bronchial asthma;

C. History of allergic disorders causing anaphylactic shock.

7. Caution should be exercised in patients with clinically severe cardiovascular disease. Myocardial infarction, uncontrolled hypertension, instable angina pectoris, congestive heart failure, uncontrolled arrhythmia’s requiring medication;

8. Pregnancy or lactating women;

9. High plasma concentration of rifampicin (inhibitor of Gd-EOB-DTPA uptake).

Study design

Design

Study type:	Interventional
Intervention model:	Other

Control: N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-04-2010
Enrollment:	230
Type:	Anticipated

Ethics review

Positive opinion

Date:	17-09-2008
Application type:	First submission

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
NTR-new	NL1460
NTR-old	NTR1529
Other	: IMP 13617
ISRCTN	ISRCTN wordt niet meer aangevraagd

Study results

Summary results
N/A