Optimal delay for hepatobiliary phase MRI with gadobenate dimeglumine

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To analyze the percentage of HCA becoming hypointens 20-25-30-35-40-45 minutes after IV contrast injection of gadobenate dimeglumine.

Ethical review	Approved WMO
Status	Pending
Health condition type	Hepatic and biliary neoplasms benign
Study type	Observational non invasive

Summary

ID

NL-OMON44618

Source
ToetsingOnline

Brief title
Delay time gadobenate dimeglumine

Condition

- Hepatic and biliary neoplasms benign

Synonym
hepatocellular adenomas, liver lesion

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Bracco,Bracco Imaging s.p.a.

Intervention

Keyword: Liver, MR

Outcome measures

Primary outcome

- Quantitative assessment: only lesions larger than 1 cm will be included (measurements in smaller lesions are less accurate). A ROI will be placed in each lesions and in the neighboring liver. Measurement will be performed at every time point including the late hepatobiliary phase.
- Qualitative assessment: all visible lesions will be included. Two readers will independently choose the turning time point where a lesion becomes hypointense to the surrounding liver. A consensus reading will be performed and interreader agreement will be evaluated.
- The percentage of lesions that become hypointense to the liver measured every 2.5 minutes during 45 minutes will be extrapolated with 95 % confidence intervals

Secondary outcome

- The effect of changing flip angle on the T1-weighting will be studied

Study description

Background summary

Rationale: Optimal delay time for hepatobiliairy imaging with MRI of gadobenate dimeglumine is not known
Objective: to analyse the optimal delay time for gadobenate dimeglumine
Study design: prospective one center observational study
Study population: patients who undergo MRI with gadobenate dimeglumine
Intervention (if applicable): observational study The patients will have to stay +/- 15 minutes longer after contrast injection in the MRI room (45 minutes instead of 25-30 minutes).
Main study parameters/endpoints: The percentage of hepatocellular adenomas that become hypointense to the liver at several time points

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: no intervention will take place. There will be no additional risks, burden or benefit for the patient.

Study objective

To analyze the percentage of HCA becoming hypointens 20-25-30-35-40-45 minutes after IV contrast injection of gadobenate dimeglumine.

Study design

- Prospective randomized cohort study
- Unicentric
- We expect final start date in February 2016. 17 patients will probably be scanned by july 2016, the second third by March 2016 and the final inclusion by October 2017.We expect that around 11 patients will be excluded since this number is expected to be finally FNHs based on the Multihance scan. If the results are promising, acquisition of additional patients will be considered in consultation with BRACCO.

Study burden and risks

There are no benefits or risks.

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

- 18 years or older
- capacity to read and interpret informed consent
- clinical indication for MRI with gadobenate dimeglumine, including delayed phase imaging after one hour

Exclusion criteria

- contraindication for MRI
- contraindication for gadobenate dimeglumine

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	15-02-2016
Enrollment:	50

Type:	Anticipated

Ethics review

Approved WMO Date:	09-02-2016
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	24-05-2016
Application type:	Amendment
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	NL49672.078.14