Primovist CT: proof of concept

Published: 15-04-2020
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To show differences in uptake of Primovist between FNHs and hepatocellular adenomas on CT.

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

Summary

ID

NL-OMON50056

Source
ToetsingOnline

Brief title
CT Primovist

Condition

- Hepatic and biliary neoplasms benign

Synonym
hepatocellular adenoma, liver lesions

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: contrast agent, CT, Primovist

Outcome measures

Primary outcome

The main study parameter is the difference in density between the FNH and the

HCA versus the surrounding liver on the Primovist-enhanced CT scan.

Secondary outcome

Difference in the liver density between the Primovist-contrast scan and the

virtual non-contrast CT scan.

Study description

Background summary

MRI with Primovist is the standard method for diagnosing focal nodular hyperplasia (FNH), and for differentiation with hepatocellular adenoma (HCA). However, some patients have contra-indications for MRI or are reluctant to the prolonged scanning time of MRI. For these people CT Primovist could be the only non-invasive alternative for diagnosis.

Study objective

To show differences in uptake of Primovist between FNHs and hepatocellular adenomas on CT.

Study design

Proof of concept study

Study burden and risks

Risks inherent to uniphasic low dose dual energy CT of the liver.

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

- Primovist-enhanced MRI scan for evaluation of liver lesion
- Diagnosis of either one FNH or one HCA
- Lesion must be at least 3 cm
- Age of 18 years or older

Exclusion criteria

- Contraindications for CT imaging
- Pregnancy
- Impaired renal function: eGRF < 45 ml/min

Study design

Design

Study phase:	2
Study type:	Observational invasive
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-09-2020
Enrollment:	10
Type:	Anticipated

Medical products/devices used

Product type:	Medicine
Brand name:	Primovist
Generic name:	dinatrium-Gd-EOB-DTPA
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO Date:	15-04-2020
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	21-10-2020
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
EudraCT	EUCTR2019-003812-30-NL
CCMO	NL70495.078.20