*T1-mapping for functional MR imaging of the liver in Primary Sclerosing Cholangitis

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Investigate whether *T1-mapping of the liver with the liver specific MRI contrast agent Gd-EOB-DTPA allows measurement of the change in liver function after ERCP treatment of a dominant stricture in PSC patients.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Hepatic and hepatobiliary disorders
Study type	Observational invasive

Summary

ID

NL-OMON40638

Source
ToetsingOnline

Brief title
*T1 in PSC

Condition

- Hepatic and hepatobiliary disorders

Synonym
Primary Sclerosing Cholangitis; Bile duct inflammation

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Gd-EOB-DTPA, Liver, PSC, T1

Outcome measures

Primary outcome

- Quantitative MRI: *T1

- MRCP/ERCP: location and degree of bile duct obstruction

Secondary outcome

- Laboratory values: e.g. AP, gGT, billirubin (as measure of cholestasis)

- Liver fat percentages (MR fat mapping)

- Bile composition (using in vitro, high-field MR Spectroscopy)

Study description

Background summary

Primary sclerosing cholangitis (PSC) is a disease of unknown origin that presents with inflammation of the intra- and extrahepatic bile ducts, which eventually become sclerotic and obstructed. Often, the acute obstruction caused by 'dominant strictures' results in accumulation of bile fluids that cause jaundice and pruritus (itch). In the course of time the ongoing inflammatory processes damage the liver parenchyma and cause fibrosis and eventually liver cirrhosis, culminating in end-stage liver disease, for which the only remaining treatment option is a liver transplant.

Current methods and techniques (laboratory values, qualitative imaging methods, ERCP) are lacking in terms of their ability to accurately monitor (PSC) disease activity and liver parenchyma function. Recent studies employing the liver specific MRI contrast agent Gd-EOB-DTPA have shown promising results. MRI with Gd-EOD-DTPA may be able to quantitatively and non-invasively (without liver biopsy) measure liver parenchyma function.

As mentioned, PSC patients often present with an acute dominant stricture and complain of severe pruritus and jaundice. In these patients an urgent MRI with MRCP (dedicated type of MRI-scan to image the bile ducts) is indicated. If a stricture is visible on MRCP, an ERCP will follow to treat the dominant

stricture with balloon dilatation. The majority of patients improve rapidly after ERCP.

The hypothesis behind this study is that the function of the liver parenchyma drained by the obstructed bile duct is temporarily reduced during the acute moment and that this function improves after ERCP treatment. By applying new, quantitative MRI-techniques such as *T1-mapping before and after ERCP-treatment we will investigate this hypothesis and try to correlate clinical (and laboratory) improvement with changes in the results of these quantitative MRI-scans.

Study objective

Investigate whether *T1-mapping of the liver with the liver specific MRI contrast agent Gd-EOB-DTPA allows measurement of the change in liver function after ERCP treatment of a dominant stricture in PSC patients.

Study design

Mono-centric observational study

Study burden and risks

Participating in this study leads to no immediate advantage for the individual participant, though treating physicians will be notified of liver function (*T1) which they potentially can use to tailor individual treatment plans. It is especially important to evaluate whether *T1-mapping of the liver using Gd-EOB-DTPA can be used to derive functional information of the liver parenchyma by comparing MRI results before and after ERCP treatment to clinical improvement (or deterioration) of PSC patients presenting with acute dominant stricture. If this is possible, *T1-mapping could be used as a tool to monitor disease activity of PSC (and other liver diseases) and liver patients in general and PSC patients in particular could profit notably of this and future research.

The additional burden for subjects consists of 2 x 5 minutes of extra MRI scan-time (added to regular clinical MRI-scans of 30 minutes).

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
- Proven prior diagnosis of Primary Sclerosing Cholangitis (based on laboratory and clinical findings and biopsy and/or ERCP and/or MRCP results)
- Clinically suspected dominant stricture causing acute pruritus and jaundice with indication for urgent MRCP and ERCP
- Written, informed consent

Exclusion criteria

- Contraindications for MRI
- Known haemochromatosis
- Chronic renal insufficiency or eGFR < 30 ml/min/1.73 m2
- Known or family history of congenital prolonged QT-syndrome
- Prior history of arrhythmia after the use of cardiac repolarisation time prolonging drugs
- Current use of cardiac repolarisation time prolonging drugs (such as class 3 anti-arrhythmic drugs (such as amiodaron or sotalol)
- Prior history of allergic reaction to gadolinium-containing compounds
- Prior history of asthma bronchiale

- Current use of beta blockers

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	13-02-2015
Enrollment:	32
Type:	Actual

Ethics review

Approved WMO

Date:	27-11-2014
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	NL50329.018.14