Clinical application of annual Liver Multiscan and MRCP+ in Primary Sclerosing Cholangitis:

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Main:The main objective is to explore the potential utility of MRCP+ and LMS in monitoring disease activity and early detection of worsening disease requiring endoscopic intervention. Secondary Objective(s): Assessment of mean, median, range and...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Bile duct disorders
Study type	Observational non invasive

Summary

ID

NL-OMON53990

Source
ToetsingOnline

Brief title
CATCH-IT

Condition

- Bile duct disorders

Synonym
Primary Sclerosing Cholangitis; Scarring of the biliary tree with unknown cause

Research involving
Human

Sponsors and support

Primary sponsor: Amsterdam UMC
Source(s) of monetary or material Support: Investigator Initiated,Perspectum Ltd. Oxford, Verenigd Koninkrijk

Intervention

Keyword: LiverMultiscan, MRCP+, PSC

Outcome measures

Primary outcome

Delta of cT1 in patients with PSC during follow-up

Secondary outcome

Mean, median and range of cT1 and MRCP+ metrics in clinically and biochemically stable patients

Variance of the delta in cT1 and MRCP+ metrics from baseline to year 1 in clinically and biochemically stable patients

Difference in mean of cT1 values in patients who needed ERCP with treatment of dominant stricture(s) in the year following LMS measurement versus those who did not need an intervention

Variance of the delta of cT1 and MRCP+ metrics in sequential scans in biochemically and/or clinically deteriorating patients.

Correlation between cT1 and MRCP+ metrics with Fibroscan and MELD-score

Correlation between cT1 and MRCP+ metrics and development of dominant strictures

Correlation between cT1 and MRCP+ metrics and incidence of CCA

Study description

Background summary

Primary sclerosing cholangitis (PSC) is a chronic progressive biliary disease that affects approximately 1200 patients in the Netherlands and around 80,000 in the Western world. It is often accompanied by ulcerative colitis (UC) or Crohn*s disease affecting the large bowel. The cause of PSC is unknown, there

is no medical therapy available that has proven to halt disease progression and the median time until death or liver transplantation is 13-21 years. Diagnosis is made by magnetic resonance cholangiography (MRC), or in the case of so called small duct disease by liver biopsy.
Due to the heterogeneous disease course and the relatively low clinical event rate of 5% per year it is difficult to predict prognosis of individual patients or to recommend any surveillance strategy for malignancies. Also, the lack of surrogate endpoints impedes performing clinical research. Recently, two new post-processing tools have been developed to characterize and quantify abnormalities in the biliary tree as well as excretory function captured by MRC. These tools called MRCP+ (quantitative magnetic resonance cholangiopancreatography +) and LiverMultiscan (LMS) hold the prospect of adequately depicting and quantifying lesions of the biliary tree as well as capturing functional derailment. However, several features must be tested before the utility of this tools in clinical patient care can be concluded.
Therefore, the aim of this study is to investigate the utility of these novel techniques in monitoring disease activity by performing MRCP+ and Liver Multiscan analysis on in standard-care annual MRI*s .

Study objective

Main:
The main objective is to explore the potential utility of MRCP+ and LMS in monitoring disease activity and early detection of worsening disease requiring endoscopic intervention.

Secondary Objective(s):
Assessment of mean, median, range and variance of MRCP+ metrics and cT1 in PSC patients at baseline and follow-up.
Finding clinically relevant deltas of cT1 (ms) and MRCP+ metrics in patients with both clinically and/or biochemically stable and worsening disease
Assessment of the correlation between changes in LMS metrics with changes in fibroscan and MELD-score.
Assessment of the correlation between (segmental) cT1 and MRCP+ metrics with the development of dominant strictures
Assessment of the correlation between cT1 values and the incidence of CCA in follow up. Assessment of the value of annual follow up by MRI with contrast, MRCP+ and LMS in the detection of cholangiocarcinoma and gallbladder carcinoma.

Study design

Prospective, single center study.

Study burden and risks

There is little burden or risk associated with this study as it only requires a

few extra sequences in addition to annual MRI that is performed routinely in standard-care settings.

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

Established diagnosis according to the IPSCSG Definitions (26)
Age >= 18
Able to give informed consent

Exclusion criteria

Known allergy for MRI contrast agents, implants non-compatible with MRI or extreme claustrophobia causing discontinuation of MRI studies.
Post livertransplantation

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	21-07-2023
Enrollment:	200
Type:	Actual

Medical products/devices used

Generic name:	Liver Multiscan en MRCP+
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	18-04-2023
Application type:	First submission
Review commission:	METC Amsterdam UMC

Approved WMO

Date:	26-10-2023
Application type:	Amendment
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	NL81069.018.22