Value of MRCP+ And Liver Multiscan in the management of Dominant strictures in primary sclerosing cholangitis

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Primary Objective: Assess the ability of MRCP+ and LMS to detect change in total biliary volume and cT1 value, 8 weeks after endoscopic treatment of dominant strictures, by a clinical decision rule.Secondary Objective(s): Assess natural course of...

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

Summary

ID

NL-OMON51520

Source
ToetsingOnline

Brief title
MALD study

Condition

- Hepatic and hepatobiliary disorders

Synonym
Dominant strictures in PSC patients; Severe narrowing of bile ducts in PSC patients

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: Dominant Strictures, Liver Multiscan, MRCP+, PSC

Outcome measures

Primary outcome

Change in total biliary volume by MRCP+ and cT1 value by LMS at 8 weeks after endoscopic treatment of dominant strictures.

Secondary outcome

Change in total biliary volume by MRCP+ and cT1 value by LMS at 8 weeks after a second endoscopic treatment of dominant strictures

Consistency of MRCP+ metrics and cT1 value by LMS when endoscopic treatment is not performed.

Correlation of MRCP+/Liver Multiscan with modified Amsterdam classic cholangiography scoring.

Correlation of imaging features of MRCP+ with classic cholangiography in individual areas of interest by two independent assessors.

Correlation of dominant strictures rated by MRCP+/Liver Multiscan with those assessed by classic definition of DS.

Reproducibility of DS not treated by ERC at baseline and at 8 weeks as determined by two independent assessors.

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 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. Several prognostic models have been developed in the past, one of which making use of cholangiography, albeit by endoscopic retrograde cholangiography (ERC). This entails an invasive procedure, which is nowadays supplanted by MRC.

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+ and Liver Multiscan (LMS) hold the prospect of adequate depicting and quantifying lesions of the biliary tree as well as capturing functional derailment.
However, before this can be concluded several features must be tested. The most important ones being (i) sensitivity to change, (ii) reproducibility, and (iii) correlation with ERC findings as gold standard. The aim of the current study is to test these features in patients that are scheduled for a therapeutic ERC.

Study objective

Primary Objective:
Assess the ability of MRCP+ and LMS to detect change in total biliary volume and cT1 value, 8 weeks after endoscopic treatment of dominant strictures, by a clinical decision rule.

Secondary Objective(s):
Assess natural course of MRCP+ and LMS metrics in subjects that are not eligible for ERC.
Assess the ability of MRCP+ and LMS to detect change in total biliary volume and cT1 value, 8 weeks after the second treatment of a DS that was unsuccessfully treated at the first ERC.
Comparison of baseline MRCP+ metrics with gold-standard ERC
Correct identification of dominant strictures (DS) eligible for treatment
Reproducibility of strictures not treated at index ERC

Study design

Prospective, singlecenter study.

Study burden and risks

There is little burden or risk associated with this study as it requires an additional sequences of LMS will be performed before ERC and one extra MRI liver, MRC and LMS sequences that would otherwise not be planned routinely on t=8w. The analysis of MRCP+ and LMS will be done after the imaging is performed. Furthermore, there is no risk attached to performing the MRCP+ and LMS as results of both software programs don*t alter therapy or diagnosis for patients.

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
Clinically suspected of a dominant stricture
Age >= 18

Able to give informed consent

Exclusion criteria

Insufficient image quality
Known allergy for MRI contrast agents
Implants that are non-compatible with MRI scanner

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	26-08-2022
Enrollment:	50
Type:	Actual

Medical products/devices used

Generic name:	Liver Multiscan (klasse IIa) en MRCP+ (klasse I)
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	05-05-2022
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	NL79773.018.22