MRCPrognosis+

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON24274

Source
NTR

Brief title
MRCPrognosis+

Health condition

Primary Sclerosing Cholangitis

Sponsors and support

Primary sponsor: Investigator initiated
Source(s) of monetary or material Support: Investigator initiated

Intervention

Outcome measures

Primary outcome

prognostic value of MRCP+ with regard to transplant-free survival

Secondary outcome

individual features of MRCP+ with regard to their prognostic performance.

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, a new post-processing tool has been developed to characterize and quantify abnormalities in the biliary tree as captured by MRC. This tool called MRCP+ holds the prospect of containing prognostic features as previously with the ERC derived cholangiographic scoring. We hypothesize that MRCP+ has predictive features in terms of time to transplantation or death.

Study objective

We hypothesize that MRCP+ has predictive features in terms of time to transplantation or death.

Study design

2021 November - Start study
2022 March - LPI
2022 April - Database completion
2022 April - Analysis of primary endpoint: C-statistic of the correlation between total bile duct volume and transplant-free survival
2022 May - Analysis of secondary endpoint: Hazard ratio of various semi-quantitative features of MRCP + and transplant-free survival.
2022 June - writing manuscript

Intervention

none

Contacts

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Eligibility criteria

Inclusion criteria

established diagnosis according to the IPSCSG Definitions
Age ≥ 18
Informed consent for review of MRCP and clinical data
available MRCs from 2010 onwards

Exclusion criteria

Inability to give informed consent
insufficient image quality
LTx at the time of imaging.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-11-2021
Enrollment:	450
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Yes

Plan description
Deidentified raw MRI data will be shared for post-processing analysis.

Ethics review

Not applicable

Application type:	Not applicable

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
NTR-new	NL9730
Other	MEC AMC : 018

Study results