MRCPrognosis+

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

Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON24274

Bron
NTR

Verkorte titel
MRCPrognosis+

Aandoening

Primary Sclerosing Cholangitis

Ondersteuning

Primaire sponsor: Investigator initiated
Overige ondersteuning: Investigator initiated

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

none

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm

Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-11-2021
Aantal proefpersonen:	450
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Ja

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

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL9730
Ander register	MEC AMC : 018

Resultaten