Follow-up of immunoglobulin G4-associated cholangitis in patients resected for presumed perihilar cholangiocarcinoma

Published: 20-07-2016
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Primary objective: to investigate the incidence of IAC in patients resected for presumed PHC.Secundary objectives:- Evaluation of the diagnostic accuracy of histological criteria for IAC compared to IgG4 qPCR test- Evaluation of disease activity by...

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

Summary

ID

NL-OMON42948

Source
ToetsingOnline

Brief title
IgG4 follow-up after biliary surgery

Condition

- Hepatic and hepatobiliary disorders

Synonym
autoimmune cholangitis, IgG4-associated cholangitis

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Follow-up, Immunoglobulin G4-associated cholangitis, Perihilar cholangiocarcinoma

Outcome measures

Primary outcome

1) Histological assessment of resection specimens by an experienced pathologist

according to diagnostic consensus criteria for IAC. The combination of >10

IgG4+ B cells/high-power field plus two out of the three following histological

criteria is considered highly suggestive of IAC:

- Lymphoplasmacytic infiltration

- Storiform (*cartwheel* or *mat-like*) fibrosis

- Obliterative phlebitis

2) Confirmation of diagnosis of IAC by laboratory assessment of IgG4 RNA and

protein levels.

Secondary outcome

1) Evaluation of diagnostic accuracy of the histological criteria for IAC

2) Evaluation of disease activity by laboratory assessment, including:

- Chemistry: ASAT, ALAT, alkaline phosphatase, gamma-GT, total bilirubin,

CA19-9, total IgG.

- Immunology: IgG subclasses.

3) Screening of serum for auto-antibodies

Study description

Background summary

Distinguishing perihilar cholangiocarcinoma (PHC; Klatskin tumor) from benign forms of sclerosing cholangitis affecting the hilar bile ducts is challenging, since histological confirmation is difficult to obtain by brush or biopsy and accurate non-invasive diagnostic tests are lacking. Immunoglobulin G4-associated cholangitis (IAC), an imitator of PHC, is a newly recognized inflammatory disease that can present as sclerosing cholangitis with/without (peri-)hilar tumor formation and is responsive to corticosteroid treatment. Occasionally, histological signs of IAC are found in resection specimens of patients that underwent surgery for presumed PHC.

Study objective

Primary objective: to investigate the incidence of IAC in patients resected for presumed PHC.

Secundary objectives:
- Evaluation of the diagnostic accuracy of histological criteria for IAC compared to IgG4 qPCR test
- Evaluation of disease activity by measurement of laboratory parameters
- Screening of serum for auto-antibodies

Study design

Observational cohort study.

Study burden and risks

Risks associated with participation are limited, since patients will be invited to visit the outpatient clinic for a one-time blood draw only (approximately 30 mL). For patients who have experienced other IgG4-RD manifestations or symptoms, re-evaluation of diagnosis may provide better insight in their disease. Patients with active disease may benefit from prednisone treatment.

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

- Patient underwent resection for presumed PHC at the AMC between 1984 and May 2016
- Histological assessment revealed a benign (sclerosing) tumor
- Patient is alive according to the municipal records database

Exclusion criteria

not applicable

Study design

Design

Study type: Observational invasive
Masking: Open (masking not used)

Control:	Uncontrolled
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	05-10-2016
Enrollment:	48
Type:	Actual

Ethics review

Approved WMO

Date:	20-07-2016
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

ID: 20357
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL58029.018.16
OMON	NL-OMON20357