

# IgG4-associated cholangitis after resection for presumed perihilar cholangiocarcinoma

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IgG4-associated cholangitis mimicks perihilar cholangiocarcinoma, resulying in patients being resected for benign disease

|                              |                            |
|------------------------------|----------------------------|
| <b>Ethical review</b>        | Positive opinion           |
| <b>Status</b>                | Recruiting                 |
| <b>Health condition type</b> | -                          |
| <b>Study type</b>            | Observational non invasive |

## Summary

### ID

NL-OMON20357

### Source

NTR

### Health condition

IgG4-associated cholangitis

## Sponsors and support

**Primary sponsor:** Academic Medical Center Amsterdam

**Source(s) of monetary or material Support:** fund=initiator=sponsor

## Intervention

## Outcome measures

### Primary outcome

Incidence of IgG4-associated cholangitis in patients resected for presumed PHC

## Secondary outcome

Evaluation of active disease with sIgG4 and qPCR test for IgG4/IgG mRNA ratio

## Study description

### Background summary

Our aim is to assess the incidence of Immunoglobulin G4-associated cholangitis (IAC) in patients resected for presumed perihilar cholangiocarcinoma (PHC). All patients that underwent resection for presumed PHC at our institution between 1984 and 2015 were included. Benign histological specimens were re-evaluated by a pathologist and scored according to the international pathological consensus criteria for IgG4-RD. Patients with benign disease who were still alive were re-evaluated to assess IgG4 serum levels and IgG4/IgG RNA ratio to detect activity of IAC.

### Study objective

IgG4-associated cholangitis mimicks perihilar cholangiocarcinoma, resulying in patients being resected for benign disease

### Study design

- re-evaluation resection specimens
- clinical re-evaluation symptoms and serummarkers

### Intervention

None

## Contacts

### Public

Eva Roos  
Amsterdam  
The Netherlands

### Scientific

Eva Roos  
Amsterdam  
The Netherlands

## Eligibility criteria

### Inclusion criteria

Resection for presumed perihilar cholangiocarcinoma

### Exclusion criteria

none

## 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:       | Recruiting  |
| Start date (anticipated): | 01-01-2016  |
| Enrollment:               | 323         |
| Type:                     | Anticipated |

## Ethics review

|                   |                  |
|-------------------|------------------|
| Positive opinion  |                  |
| Date:             | 15-05-2017       |
| Application type: | First submission |

## Study registrations

### Followed up by the following (possibly more current) registration

ID: 42948

Bron: ToetsingOnline

Titel:

### Other (possibly less up-to-date) registrations in this register

No registrations found.

### In other registers

| Register | ID             |
|----------|----------------|
| NTR-new  | NL6287         |
| NTR-old  | NTR6461        |
| CCMO     | NL58029.018.16 |
| OMON     | NL-OMON42948   |

## Study results