

Epidemiology and Natural History of, and risk factors for Primary Sclerosing Cholangitis & Primary Biliary Cirrhosis in central Netherlands.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON27701

Source

NTR

Brief title

Epi PSC PBC

Health condition

primary sclerosing cholangitis
primary biliary cirrhosis
population-based epidemiology
case-control study
risk factors
natural history

Sponsors and support

Primary sponsor: C.IJ. Ponsioen, MD PhD

Source(s) of monetary or material Support: C.IJ. Ponsioen, MD PhD

Intervention

Outcome measures

Primary outcome

1. True population-based point-prevalence (2006) and inferred incidence of newly diagnosed cases (2000-2006);
2. Natural history with respect to death, liver transplantation, occurrence of cholangiocarcinoma and colorectal carcinoma.

Secondary outcome

Relative risk determination of several putative environmental, behavioural and genetic risk factors between PSC and PBC as well as background population.

Study description

Background summary

Background of the study:

Primary sclerosing cholangitis (PSC) and primary biliary cirrhosis (PBC) are relatively rare liver diseases that in most cases lead to liver failure in 10-20 year. Nowadays, both diseases are regarded as immune dysbalance disease entities, but in fact the aetiology is unknown. Regarding the prevalence, incidence and natural history of PSC and PBC there are only crude estimates. True population-based studies have not been carried out.

Objective of the study:

Main objectives: To obtain true population-based prevalence and incidence figures, as well as insight in the natural history of PSC and PBC in The Netherlands. Secondary objectives: to determine risk factors correlated with PSC and PBC respectively, such as environmental factors, behavioural factors and genetic factors; to build two large inception cohorts of PSC and PBC patients for future studies.

Study design:

Observational longitudinal cohort study with case-control substudies. In all hospitals of the Gut-club-, Stichts Genootschap-, and Duamutef Society members all PSC and PBC patients from 2000-2006 will be traced via several independent local search strategies. Charts will be reviewed for relevant data. Follow-up data will be collected by yearly correspondence.

Study population:

All 45 general and academic hospitals of the provinces of North-Holland, Flevoland, Overijssel, Utrecht, Gelderland and Drenthe covering a population of more than 8,000,000 inhabitants, will participate. All cases ≥ 18 years of age meeting accepted criteria for a diagnosis of PSC or PBC will be included. Two controlgroups will be accrued; one IBD-patients group and one general GI-outpatient group.

15-jul-2017: Most important changes

As the epidemiological research questions have been answered yet (Boonstra et al., 2013), but many questions about the natural course and risk factors remain, this study will continue in a adapted format. The study area is extended, all Dutch PSC patients can be included. Patients will receive periodical digital questionnaires. For follow-up we will ask local doctors to send us a letter yearly.

Study objective

Primary sclerosing cholangitis (PSC) and primary biliary cirrhosis (PBC) are relatively rare liver diseases that in most cases lead to liver failure in 10-20 year. Nowadays, both diseases are regarded as immune dysbalance disease entities, but in fact the aetiology is unknown. Regarding the prevalence, incidence and natural history of PSC and PBC there are only crude estimates. True population-based studies have not been carried out.

Study design

N/A

Intervention

N/A

Contacts

Public

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Eligibility criteria

Inclusion criteria

1. Age \geq 18 years;
2. At least at one point during the period 1-1-2000 and 1-1-2007 resident in the abovementioned area;
3. Diagnosis of PSC according to established criteria and after revision of the principal investigator;
4. Diagnosis of PBC according to established criteria and after revision of the principal investigator, i.e. elevated serum alkaline phosphatase, positive anti-mitochondrial antibody titre and no signs of auto-immune hepatitis or drug-induced hepatitis;
5. Controls must have no history of liver disease and normal routine liver tests.

Exclusion criteria

Inability to give informed consent.

Study design

Design

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

Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	01-06-2007
Enrollment:	1800
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion	
Date:	16-03-2011
Application type:	First submission

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	NL2684
NTR-old	NTR2813
Other	METC UMC Utrecht : 06-267/E
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results

N/A