

Epidemiology and natural history of and risk factors for primary sclerosing cholangitis & primary biliary cirrhosis in the Netherlands

Published: 17-04-2007

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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,...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Hepatic and hepatobiliary disorders
Study type	Observational non invasive

Summary

ID

NL-OMON47329

Source

ToetsingOnline

Brief title

Epidemiology of PSC/PBC

Condition

- Hepatic and hepatobiliary disorders

Synonym

Chronic cholestatic liver disease

Research involving

Human

Sponsors and support

Primary sponsor: 1. Amsterdams Gastroenterologisch Genootschap, 2. Stichts

Genootschap, 3. Duamutef

Source(s) of monetary or material Support: ZonMW, Tramedico, Tramedico b.v. als subsidiegever

Intervention

Keyword: incidence, natural history, prevalence, risk factors

Outcome measures

Primary outcome

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

Secondary outcome

Secondary endpoints: Odds ratio and relative risk determination of several putative environmental, behavioural and genetic risk factors between PSC and PBC as well as control groups. Among these are smoking behaviour, previous appendectomy, familial occurrence, previous Chlamydia infection, CCL25 polymorphisms, and the protective effect on the natural history of immunomodulatory medication.

Study description

Background summary

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 objective

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 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 burden and risks

Burden with participation consists of filling in a single leaflet 9-item questionnaire and drawing of two extra blood samples during routine outpatient blood testing. No extra visits are scheduled (only for patients included before 2013).

Periodic digital questionnaires.

Contacts

Public

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Scientific

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

Established diagnosis of PSC

Established diagnosis of PBC

age > 18.

Resident in the Netherlands.

Exclusion criteria

Inability to give informed consent

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Other

Recruitment

NL
Recruitment status: Recruiting
Start date (anticipated): 08-12-2007
Enrollment: 1100
Type: Actual

Ethics review

Approved WMO
Date: 17-04-2007
Application type: First submission
Review commission: METC NedMec

Approved WMO
Date: 24-02-2009
Application type: Amendment
Review commission: METC NedMec

Approved WMO
Date: 02-06-2009
Application type: Amendment
Review commission: METC NedMec

Approved WMO
Date: 08-06-2010
Application type: Amendment
Review commission: METC NedMec

Approved WMO
Date: 14-06-2016
Application type: Amendment
Review commission: METC NedMec

Approved WMO
Date: 07-06-2017
Application type: Amendment
Review commission: METC NedMec

Approved WMO
Date: 24-08-2017

Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	27-02-2018
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	31-01-2019
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	10-08-2020
Application type:	Amendment
Review commission:	METC NedMec

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
CCMO	NL14614.041.06