

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

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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...

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON27701

Bron

NTR

Verkorte titel

Epi PSC PBC

Aandoening

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

Ondersteuning

Primaire sponsor: C.IJ. Ponsioen, MD PhD

Overige ondersteuning: C.IJ. Ponsioen, MD PhD

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

N/A

Onderzoeksproduct en/of interventie

N/A

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Inability to give informed consent.

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Parallel
Toewijzing:	N.v.t. / één studie arm
Blinding:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland	
Status:	Werving gestart
(Verwachte) startdatum:	01-06-2007
Aantal proefpersonen:	1800
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies	
Datum:	16-03-2011
Soort:	Eerste indiening

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

Resultaten

Samenvatting resultaten

N/A