The health burden of Primary Biliary Cirrhosis in Switzerland

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Project Title:	The health burden of Primary Biliary Cirrhosis (PBC) in Switzerland
Project Plan Version and Date:	Version 05.05, 22.10.2015
Risk categorisation:	A
Type of Research:	Research project in which health-related medical data is used for further research.
Project design:	Cross-sectional study of prevalence of Primary Biliary Cirrhosis (PBC) in Switzerland.
Background and Rationale:	PBC is a rare, autoimmune, cholestatic liver disease with genetic and environmental pathogenetic factors. Data about epidemiology of PBC in Switzerland are completely lacking. Epidemiology can be a powerful tool in yielding important clues as to burden and etiology of diseases. In addition, our study will be the first one carried out in the country on PBC, and therefore will raise disease awareness and create a network.
Objective:	To generate data about the health burden of PBC in Switzerland.
Aim:	To describe prevalence, risk factors and characteristics of patients with PBC in Switzerland.
Inclusion / Exclusion criteria:	Diagnosis of PBC, defined according to the guidelines of the European Association for the Study of the Liver (EASL).
Project Duration, schedule:	The project is estimated to begin in December 2015. Data collection, data analysis and publication will be completed by 30.9.2016.

Procedures:

All swiss hepatology centres have been invited to participate. In order to increase patient recruitment, all gastroenterologists will be invited as well.
Patients will be informed by letter about the further use of their medical data in coded form for research purpose, according to article 32 of the Swiss Ordinance on Human Research of September the 20th 2013. Registered mail

(A plus) will be used. A form will be included to be used by the patient in case of refusal in being included in the study. The form must be sent back to the centre within one month in case of refusal. For deceased or not to be found subjects, the letters will be undelivered and returned to the sender. Data from these patients will be collected according to article 34 of the Swiss Human Research Act.

The following variables for each included patient will be assessed:

- Sex
- age at diagnosis
- region of residence at time of diagnosis
- ethnicity
- body weight and height at diagnosis
- date of first specialized centre visit
- date of first AMA positive test (or alternative markers if AMA-negative PBC)
- ANA, antiM2, PBC specific ANA (sp100, gp210) at diagnosis
- Biopsy proven overlap AIH, date of biopsy
- Autoimmune skin disorders
- presence of diabetes
- liver transplantation and date
- date and cause (hepatic or extrahepatic) of death
- start date of UDCA and dosage
- alkaline phosphatase at diagnosis and after 1 year UDCA treatment
- platelet count and albumin at diagnosis
- AST, ALT and bilirubin after 1 year UDCA treatment
- transient elastography value at diagnosis (if available)