Summary – SASL Swiss Cirrhosis Cohort Study (SSciCos)

Project Leader	PD Dr. Dr. Christine Bernsmeier, Basel
Co-Project Leader	Prof. Dr. Dr. Annalisa Berzigotti, Bern
Project Title:	SASL Swiss Cirrhosis Cohort Study
Short Title/Project ID:	SSciCoS
Protocol Version and Date:	1, 24.05.2022
Research legislation:	Ordinance on human research with the exception of clinical trials (HRO)
Type of Research	Research project involving human subjects
Risk category	Risk category A according to ordinance HFV Art. 7

Background and Rationale:

Cirrhosis is late-stage liver disease resulting as a consequence of diverse underlying aetiologies, which occurs when scar tissue (fibrosis) replaces healthy liver tissue. The prevalence of cirrhosis is estimated 0.3% of the population and is continually rising due to the increasing load of chronic liver disease, especially alcoholic and non-alcoholic fatty liver disease. Worldwide cirrhosis was estimated to be responsible for one million deaths annually, equating to 2% of all deaths, and is the leading cause for liver transplantation. It is a multisystem inflammatory disease and can be sub-classified into distinct clinical prognostic stages, with a very high 1-year mortality ranging from 1% to 57% depending on the stage. Patients with cirrhosis experience several stressors and often report a decrease in their quality of life, especially due to high symptom burden.

Currently for patients with end-stage cirrhosis there are no treatment options other than transplantation, a medically and ethically challenging procedure. The challenge therefore is to prevent the need for liver transplantation in as many patients with cirrhosis as possible.

In order to reach this aim, patients with cirrhosis should be identified and followed regularly according to the highest standard of current knowledge. Numerous aspects of the disease need to be detailed: its epidemiology in Switzerland, its pathophysiology including the mechanism of scar tissue generation and resolution, the associated immune dysfunction and subsequent organ failures, disease related psychosocial and behavioural factors, perceived burden of liver cirrhosis in patients, diagnostic and prognostic biomarkers for disease dynamics, both progression and regression of disease, and stage-specific therapeutic strategies.

Objective(s):

Systematically and longitudinally record epidemiological, clinical, histological, psychosocial and patient-reported data and biobank biological material from patients with cirrhosis

Project design:

National prospective long-term multicentre observational cohort study following patients with cirrhosis

Inclusion/Exclusion criteria:

Inclusion criteria: A) Patients with chronic liver disease and histologically proven cirrhosis
B) Control subjects with no signs of cirrhosis

Exclusion criteria: - Age <18 years
- patients who developed HCC

Procedures:
- Prospective recruitment of patients with cirrhosis, acute decompensation, pathological and healthy controls
- Blood sampling at day of inclusion and in 6-monthly intervals for stable cirrhotic patients; at day of inclusion and on days 3, 7, 14 and 28 for acute decompensation or acute-on-chronic liver failure patients; assessment of clinical, psychosocial/behavioural and patient-reported data in parallel with blood sampling;
- Biobanking of PBMCs and serum/plasma samples
- Biobanking of other biological material if sampled for clinical reasons (liver biopsies, ascites, urine, gut mucosa, lymph nodes)

Number of Subjects: > 500 patients, 250 control subjects (for all sites combined)
Project Duration: Long-term cohort, from 2022 onwards

Project Centres:
University Centre for Gastrointestinal and Liver Diseases, Basel
Department of Visceral Surgery and Medicine, University Hospital of Berne
Gastroenterology and Hepatology, Cantonal Hospital St. Gallen
Gastroenterology and Hepatology, University Hospital Geneva
Gastroenterology and Hepatology, Lausanne University Hospital
Gastroenterology and Hepatology, University Hospital Zurich
Gastroenterology and Hepatology, Cantonal Hospital Ticino
Ticino Liver Centre
Digestive Diseases Institute GastroZentrum, Hirslanden Clinic Zurich
Arud Centre for Addiction Medicine, Zurich

Risk-Benefit statement
There is no risk for patients to participate as the clinical and psychosocial data will be assessed as part of the clinical routine, additional bloods taken will not harm the patient and other biological material will be taken only if indicated for their clinical care. The patients will not benefit themselves from participating in the study.
Prospectively and systematically assessing data and biological material from patients with cirrhosis may lead to development of novel biomarkers or targeted stage-specific therapies for patients with cirrhosis.