Forum medizinische Register Schweiz

Auszug aus der Register Online-Plattform der FMH-Website (www.fmh.ch > Themen > Qualität / SAQM > Register).

NAFLD Kohorte – Prospektive Kohorte und Biobank von Patienten mit nicht-alkoholischer Fettlebererkrankung (NAFLD Kohortenstudie)

Kurzbeschreibung

The NAFLD Cohort Study is a single-center, national, retrospective and prospective cohort aimed at collecting high-quality baseline and follow-up data on patients diagnosed with NAFLD, NASH, or MAFLD. The primary objective is to establish a unified cohort using standardized criteria to support future research into the clinical presentation, natural history, treatment response, genetic and metabolic risk factors, and overall disease outcomes. This cohort will facilitate the collection of clinical data and biological samples, enabling comprehensive studies on genetic, serological, microbiological, and immunological aspects of NAFLD/NASH/MAFLD. The project will provide a robust platform for investigating treatment options and patient responses over time. The cohort includes patients from Epatocentro Ticino and collaborating clinicians. Biological samples will be collected at different time-points and stored at -80°C. Clinical data, including patient demographics, comorbidities, and ongoing therapies, will be recorded using the REDCap® Database for Electronic Data Capture (EDC).

Weitere Informationen

Fachrichtung	Andere: Hepatology
Registertyp	Klinisch
Datenarten	Soziodemographie, Krankheit/ Diagnose, Intervention/Therapie
Status	Aktiv, seit 2023
Population	Nonalcoholic Fatty Liver Disease (NAFLD)
Periodizität	Kontinuierlich
Geografische Abdeckung	National, Currently, the cohort is single-center, with patients enrolled in Lugano at Epatocentro Ticino.

Trägerschaft	Andere: Fondazione Epatocentro Ticino
Finanzierung	Privat
Schnittstellen	
Datenerfassung	In digitaler Form (Computer-unterstützte Dateneingabe), RedCap
In digitaler Form (Computer-unterstützte Dateneingabe)	1h
Teilnahmepflicht	Ja,
Teilnahmemöglichkeit	Nein
Einwilligung Patienten	Ja
Personenbezug	Anonymisiert (kein direkter Personenbezug möglich)
Datenschutz	Data generation, transmission, storage and analysis of health-related personal data and the storage of biological samples within this project will follow strictly the current Swiss legal requirements for data protection and will be performed according to the Ordinance HRO Art. 5. Project data will be handled with uttermost discretion and is only accessible to authorized personnel who require the data to fulfil their duties within the scope of the research project. Password protection ensures that only authorized and trained staff can enter the eCRF system (REDCap®) to view, add or edit data according to their permissions. Such modifications will be visible in the audit trail. User training is performed by the CTU of Fondazione Epatocentro according to SOPs. Each enrolled patient is identified with a unique code. The code is assigned by the authorized personnel of Epatocentro Ticino (EPT) and managed by the CTU of Fondazione Epatocentro.
Datenzugang	Ja, Researchers may request data after approval by the study's scientific committee.
Qualitätssicherung	The Data Manager of the CTU of Fondazione Epatocentro Ticino will enter the data from the project specific paper forms into an electronic data capture system (REDCap®). All the personnel involved in the project will be trained for their specific tasks and on all important project related aspects. Moreover, all team will follow the study-specific standard operating procedures (SOPs) guaranteeing the data and sample quality.
Berichterstattung	Nein

Betreiberinstitution

Fondazione Epatocentro Ticino
Via Soldino 9
6900 Lugano

Kontaktperson	Andreas Cerny
E-Mail:	andreas.cerny@hin.ch
Tel.	0919106570

Website	https://www.epatocentro.ch/it/La-Fondazione

https://clinicaltrials.gov/study/NCT07051863