CALMET - Multicentric Prospective Cohort Study of Patients with Chronic Alcoholic and/or Metabolic Liver Disease

Head :De Ledinghen Victor, INSERM U889 UNIVERSITE VICTOR SEGALEN
Cales , HIFIH, UPRES EA 3859 IFR 132
Mathurin , INSERM U795

Last update : 07/30/2014 | Version : 1 | ID : 60163

General

Identification

Detailed name	Multicentric Prospective Cohort Study of Patients with Chronic Alcoholic and/or Metabolic Liver Disease
Sign or acronym	CALMET
CNIL registration number, number and date of CPP agreement, AFSSAPS (French Health Products Safety Agency) authorisation	CNIL: DR-2011-204

General Aspects

Medical area	Endocrinology and metabolism
Health determinants	Genetic
Others (details)	Hepatocellular carcinoma, cirrhosis
Keywords	decompensation, liver failure, portal hypertension, cirrhosis, gastrointestinal bleeding, ascites, renal failure, encephalopathy, guided liver biopsy, Health episodes, aggravation, infection, prevention, care, treatment, CHC, imaging, diagnosis, death

Scientific investigator(s) (Contact)

Name of the director	De Ledinghen
Surname	Victor
Address	33000 BORDEAUX
Phone	+ 33 (0)5 57 65 64 39
Email	victor.deledinghen@chu-bordeaux.fr

Unit	INSERM U889 UNIVERSITE VICTOR SEGALEN
Organization	CENTRE HOSPITALIER UNIVERSITAIRE DE
Name of the director	Cales
Address	Angers
Phone	+ 33 (0)2 41 35 34 07
Email	PaCales@chu-angers.fr
Unit	HIFIH, UPRES EA 3859 IFR 132
Organization	CHU
Name of the director	Mathurin
Address	59000 LILLE
Phone	+ 33 (0)3 20 44 56 09
Email	p-mathurin@chru-lille.fr
Unit	INSERM U795
Organization	CHRU

Collaborations

Participation in projects, networks and consortia	Yes

Funding

Funding status	Public
Details	- SOUTIEN DE COHORTES 2009 DANS LE CADRE DES « TRÈS GRANDES INFRASTRUCTURES DE RECHERCHE » (TGIR) - INSERM Recherche de financements additionnels

Governance of the database

Sponsor(s) or organisation(s) responsible	CHU Bordeaux
Organisation status	Public

Additional contact

Main features

Type of database	
Type of database	Study databases
Study databases (details)	Cohort study
Database recruitment is carried out by an intermediary	A selection of health institutions and services
Database recruitment is carried out as part of an interventional study	No
Additional information regarding sample selection.	Inclusion method: Prospective
Database objective	
Main objective	General objective: These studies will allow us: - to prospectively determine the impact of different alcoholic and/or metabolic cirrhosis complications and to investigate factors associated with the onset of each event (CHC, decompensation, death), so as to construct and validate predictive scoring. These results will allow the assessment of different levels of risk in order to adapt clinical treatment. The large number of patients should determine whether there are differences concerning the impact of complications and predictive factors according to cirrhosis aetiology. - to identify predictive factors concerning the onset of clinical complications from prospectively gathered biological samples (serum, plasma, DNA), and to evaluate their relevance regarding known factors for viral cirrhosis. This research will benefit from recent advances in biology, particularly in the field of genomics and proteomics. The identification of new factors could improve predictive factors and provide avenues for basic research through nested studies. - to assess the impact of different treatments (alcohol withdrawal, management of diabetes, arterial hypertension, weight loss, etc.) concerning clinical complications and to determine possible treatment modifications which could result in this. The efficacy and safety of these treatments will also be evaluated using a large population receiving treatment under real life conditions. Secondary objective: These studies may use the prospective cohort database along with collected samples, allowing for an optimal use of resources. However, they must include a specific component that requires independent organisation and financing, and that only involves a portion of the included

	population. Relevant areas are quite diverse (immunology, genetics, metabolism, diabetes, cardiology, imaging, biostatistics, quality of life, pharmacology, health economics, etc.). Some of these studies will be achievable in the short-term.
Inclusion criteria	- over 18 years of age; - liver disease whose severity was determined by hepatic puncture biopsy (HPB) or non-invasive markers of fibrosis or FibroScan: - HPB with bridging fibrosis or cirrhosis (regardless of the date and method of liver sample); - Fibrotest greater than 0.58 and at least 6 months old - Measurement of liver stiffness by FibroScan greater than 7.9 kPa (with IQR/LSM less than 0.30) older than 6 months; - no previous decompensated cirrhosis (gastrointestinal bleeding or clinical ascites) or CHC (treated or untreated); - existence of criteria demonstrating a history or continuance of chronic alcohol use, defined by consumption of 30 g per day for men and 20 g per day for women for at least 10 years (more than 21 drinks per week for men and 14 drinks per week for women); - presence of 3 metabolic syndrome criteria: increased waist circumference (greater than 102 cm for men, greater than 88 cm for women), diabetes or elevated fasting blood glucose (greater than or equal to 6.1 mmol /l), treated or untreated arterial hypertension (greater than or equal to 130/85 mmHg), decreased HDL cholesterol (less than 1.04 mmol/l for men, less than 1.28 mmol/l for women) elevated triglycerides (greater than 1.6 mmol /l - Lancet 2005); - individuals covered by social security insurance; - who have received clear and honest information regarding the study and given written consent.
Population type	
Age	Adulthood (19 to 24 years) Adulthood (25 to 44 years) Adulthood (45 to 64 years) Elderly (65 to 79 years) Great age (80 years and more)
Population covered	Sick population
Gender	Male Woman
Geography area	National
Detail of the geography area	Multicentric cohort throughout France (60 centres)

Data collection

Dates

Date of first collection (YYYY or MM/YYYY)	2011
Date of last collection (YYYY or MM/YYYY)	2018

Size of the database

Size of the database (number of individuals)	< 500 individuals
Details of the number of individuals	385

Data

Database activity	Current data collection
Type of data collected	Clinical data Declarative data Paraclinical data Biological data
Clinical data (detail)	Direct physical measures Medical registration
Declarative data (detail)	Paper self-questionnaire
Paraclinical data (detail)	FIBROSCAN Imaging ? HPB (IF CARRIED OUT); BRUNT-KLEINER SCORE ? CALCULATION OF DIFFERENT NON-INVASIVE STUDIED FIBROSIS SCORES WILL BE AS FOLLOWS: FIBROMETER, FIBROTEST, NAFLD SCORE, HEPASCORE, MAYO CLINIC SCORE (WHICH DISTINGUISHES NAFLD FROM ALCHOLIC LIVER DISEASE AND USES THE FOLLOWING PARAMETERS: MCV, AST, ALT, WEIGHT, HEIGHT, GENDER: HTTP://MAYOCLINIC.ORG/GI-RST/MAYOMODEL10.HTML) (REF: DUNN W, ANGULO P ET AL. GASTROENTEROLOGY 2006 ;131 :1057-63).
Biological data (detail)	Type of samples taken: - standard blood sample: NFS platelets, TP, AST, ALT, GGT, alkaline phosphatase, bilirubin, albumin, creatinine, urea, fasting glucose, total cholesterol, HDL and LDL cholesterol, triglycerides, alpha-fetoprotein; - Fasting insulin (for HOMA calculation) alpha-2-macroglobulin, haptoglobin, hyaluronic acid,

	apolipoprotein A-I.
Presence of a biobank	Yes
Contents of biobank	Serum Plasma DNA
Details of biobank content	Serum bank, plasma bank, DNA bank
Health parameters studied	Health event/morbidity Health event/mortality
Procedures	
Data collection method	Self-administered questionnaire: from a paper questionnaire (manual input) Interview: from a paper questionnaire (manual input) Clinical examination: direct input Biological analysis: direct input
Participant monitoring	Yes
Details on monitoring of participants	4 years
Links to administrative sources	No
Promotion and access	
Promotion	
Link to the document	http://www.ncbi.nlm.nih.gov/pubmed/18394858
Access	
Terms of data access (charter for data provision, format of data, availability delay)	Data may be used by academic teams. Access for each nested study using clinical data and/or samples collected from the cohort is subject to specific projects that have an indicated link to the cohort. All independent aspects regarding the associated project (clinical data, questionnaires, additional tests, bioassays etc.) will require specific funding. Research projects must first be discussed and approved by the Scientific Council, either at annual meetings, or after distribution via email (if necessary). In any case, clinical data from the common database or stored biological samples can not be used in a study by a member of the Scientific Council or by an investigator (or any other persons) without the consent of the group according to the regulations stated above. In the case of a disagreement regarding the use of data

	or samples, voting will be carried out in order ??to choose between the different proposals (rules to be defined). Implementation of nested studies will be subject to prior authorisation and review from the appropriate regulatory bodies. Data may not be used by industrial teams.
Access to aggregated data	Access on specific project only
Access to individual data	Access on specific project only