- Longitudinal prospectice study on hepatocellular carcinoma in alcoholic or HCV-related cirrhotic patients

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General

Identification

Detailed name	Longitudinal prospectice study on hepatocellular carcinoma in alcoholic or HCV-related cirrhotic patients
CNIL registration number, number and date of CPP agreement, AFSSAPS (French Health Products Safety Agency) authorisation	CNIL n°1254760, labelled Biological Resources Center (GH PSSD)

General Aspects

Medical area	Infectious diseases
Health determinants	Addictions
Keywords	Alcoholic cirrhosis, Hepatitis C virus, hepatocellular carcinoma, ?-fetoprotein, liver biopsy, liver ultrasonography., HCV, HCC, genetics

Scientific investigator(s) (Contact)

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Organization	AP-HP
Collaborations	
Funding	
Funding status	Mixed
Details	University Paris 13, Association Française pour l'Etude du Foie (AFEF), Institut de recherches scientifiques sur les boissons (IREB), AP-HP.
Governance of the database	
Sponsor(s) or organisation(s) responsible	INSERM
Organisation status	Public
Sponsor(s) or organisation(s) responsible	AP-HP
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.	Participation in the study was offered to all new patients who were consecutively referred to the liver unit of the Jean Verdier Hospital for diagnosis and management of cirrhosis since January 1999 and who fulfilled the inclusion criteria.
Database objective	
Main objective	The present database aims at enabling the study of the relationship between alcoholic cirrhosis or HCV-related cirrhosis and hepatocellular carcinoma while

	providing information on the clinical follow-up of patients. The database is complemented by biological samples : cryopreserved DNA and serum of patients included in the study, in order to enable genetic and molecular analysis in cirrhotic patients.
Inclusion criteria	- histologically proven cirrhosis, whatever the time of biopsy; - no infection from the human immunodeficiency virus or hepatitis B virus; - no evidence of HCC at the time of inclusion as judged by negative ultrasonographic findings, and a serum ?-fetoprotein (AFP) level of inferior to 50 ng/ml; - residence in France; - acceptance of a regular follow-up and periodical HCC screening; - Caucasian origin; - written informed consent for the use of frozen DNA.
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	Regional
French regions covered by the database	Île-de-France
Detail of the geography area	Jean Verdier Hospital, Bondy, France
Data collection	
Dates	
Date of first collection (YYYY or MM/YYYY)	01/1999
Size of the database	
Size of the database (number of individuals)	[500-1000[individuals

Details of the number of individuals	532: - 253 HCV-related cirrhotic patients - 279 alcoholic cirrhotic patients
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
Details of collected clinical data	Socio-demographic characteristics, Body Mass Index, past history of diabetes mellitus.
Declarative data (detail)	Face to face interview
Details of collected declarative data	Socio-demographic characteristics, Body Mass Index, past history of diabetes mellitus.
Paraclinical data (detail)	presence of ascites or hepatic encephalopathy, liver biopsy for all patients, virological data for HCV-infected patients.
Biological data (detail)	Serum bilirubin, albumin and prothrombin levels, serum alanine-aminotransferase activity, and serum aspartate-aminotransferase activity.
Presence of a biobank	Yes
Contents of biobank	Whole blood Serum Tissues DNA
Details of biobank content	Cryopreserved DNA.
Health parameters studied	Health event/morbidity Health event/mortality Health care consumption and services
Care consumption (detail)	Hospitalization Medical/paramedical consultation Medicines consumption
Procedures	
Quality procedure(s) used	Labelled Biological Resources Center (CRB) GH PSSD

Participant monitoring	Yes
Details on monitoring of participants	All patients were followed-up and evaluated after their inclusion at a minimum of 6-month intervals by physical examination, liver ultrasonography, and serum AFP level assessment, and in case HCC was suspected: computed tomodensitometry, and/or magnetic-resonance imaging and/or a guided liver biopsy were performed according to the recommendations of the Barcelona Conference. HCC was diagnosed according to one of the following criteria: histological evidence or convergent demonstration of a focal lesion superior to 2 cm in size, and arterial hypervascularization, as assessed by two different imaging techniques, or a combination of one imaging technique that showed this morphological aspect plus a serum AFP level superior or equal to 400 ng/ml.
Links to administrative sources	No

Promotion and access

Promotion

Link to the document	http://www.cghjournal.org/article/S1542-3565%2804%2900718-9/fulltext
Link to the document	http://cancerres.aacrjournals.org/content/66/5/2844.long
Link to the document	http://www.ncbi.nlm.nih.gov/pubmed/17413295
Link to the document	http://www.cghjournal.org/article/S1542-3565%2806%2901200-6/fulltext
Link to the document	http://www.gastrojournal.org/article/S0016-5085%2807%2901918-X/fulltext
Link to the document	http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2683997/
Link to the document	http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2744164/
Link to the document	http://onlinelibrary.wiley.com/doi/10.1002/hep.23187/full
Link to the document	http://cebp.aacrjournals.org/content/20/7/1439.long
Link to the document	http://europepmc.org/abstract/MED/21907168/reload

Link to the document	http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3527286/
Link to the document	http://www.sciencedirect.com/science/article/pii/S0168827812007763
Link to the document	http://www.jhep-elsevier.com/article/S0168-8278%2814%2900264-5/abstract

Access	
Terms of data access (charter for data provision, format of data, availability delay)	For more information, contact the scientific manager.
Access to aggregated data	Access on specific project only
Access to individual data	Access on specific project only