CIRCE - Case-Control Study on Environmental, Metabolic and Nutritional Factors of Hepatocellular Carcinoma in Cirrhotic Patients

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Last update : 05/12/2015 | Version : 1 | ID : 9117

General

Identification

Detailed name	Case-Control Study on Environmental, Metabolic and Nutritional Factors of Hepatocellular Carcinoma in Cirrhotic Patients
Sign or acronym	CIRCE
CNIL registration number, number and date of CPP agreement, AFSSAPS (French Health Products Safety Agency) authorisation	CNIL, CPP

General Aspects

Medical area	Gastroenterology et hepatology
Health determinants	Climate Geography Lifestyle and behavior Nutrition Occupation Pollution
Keywords	carcinogenesis, cirrhosis, HCC, nutrition, physical activity

Scientific investigator(s) (Contact)

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Organization	CHU de
Collaborations	
Participation in projects, networks and consortia	Yes
Details	ProSpec study (proteomics)
Funding	
Funding status	Public
Details	Dijon UHC
Governance of the database	
Sponsor(s) or organisation(s) responsible	CHU de Dijon
Organisation status	Public
Additional contact	
Main features	
Type of database	
Type of database	Study databases
Study databases (details)	Case control 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
Database objective	
Main objective	Little data are available on carcinogenesis mechanisms in cirrhotic patients and associated risk factors. This clinical, biochemical and molecular case-control study may be relevant to the understanding of nutrition, physical activity, metabolic syndrome and lipids (CiRCE Lip's study) in the development of hepatocellular carcinoma (HCC), regardless of the aetiology of the underlying cirrhosis. It will open new perspectives in HCC prevention through dietary counselling and metabolic

	syndrome therapeutics and identify predictive HCC markers in cirrhotic patients (CiRCE ProSpec study), as well as new therapeutic targets for the treatment of cancer with challenging prognosis.
Inclusion criteria	- Aged 35 or over; - Informed consent. Cirrhotic cases: - Patients with hepatocellular carcinoma cases from liver cirrhosis, regardless of the cause of the cirrhosis. - Criteria for hepatocellular carcinoma diagnosis: European Association for Study of the Liver (EASL); Focal hepatic lesions greater or equal to 2 cm in diameter: - Alpha-fetoprotein (AFP) below 400 ng/ml: nodules must be identified by at least two morphological examinations (abdominal ultrasound, angiography, CT or MRI); - AFP over 400 ng/ml: lesion seen in a single imaging procedure; Focal hepatic lesions less 2 cm in diameter: - Lesions 1 to 2 cm in diameter: use of fine-needle aspiration with biopsy; - Lesions less than 1 cm: serial abdominal ultrasound every 3 months until the lesion exceeds 1 cm in size so that biopsy becomes possible. These cases will be included at time of diagnosis. Cirrhotic control patients: - Histological confirmation by liver biopsy or in the absence of biopsy: - In patients with no portal thrombosis at Doppler imaging, on the presence of portal hypertension confirmed by biological, morphological, hepatic venous pressure measurements or upper endoscopy. - In patients with portal thrombosis, on the presence of portal hypertension associated with clinical or morphological signs of cirrhosis. - Biological signs of hepatocellular failure. - Lack of HCC at baseline through imaging examinations. Exclusion criteria: - Other cancer; - HIV infection; - Major somatic or psychiatric illness not compatible

	for inclusion in the study. 1,179 cirrhotic patients with (436 cases) or without (743 controls) HCC were enrolled in the CiRCE study.
Population type	
Age	Adulthood (25 to 44 years) Adulthood (45 to 64 years) Elderly (65 to 79 years)
Population covered	Sick population
Gender	Male Woman
Geography area	National
Detail of the geography area	Besançon, Dijon, Metz, Reims, Strasbourg and Vandœuvre-lès-Nancy.
Data collection	
Dates	
Date of first collection (YYYY or MM/YYYY)	06/2008
Size of the database	
Size of the database (number of individuals)	[1000-10 000[individuals
Details of the number of individuals	1,179: - 436 cas/cases or without - 743 témoins/controls
Data	
Database activity	Data collection completed
Type of data collected	Clinical data Declarative data Paraclinical data Biological data
Clinical data (detail)	Medical registration
Details of collected clinical data	--
Declarative data (detail)	Face to face interview

Details of collected declarative data	--
Paraclinical data (detail)	Ultrasound, CT, MRI.
Biological data (detail)	Dosage of vitamin B12 and folates.
Presence of a biobank	Yes
Contents of biobank	Serum Plasma DNA
Details of biobank content	Serum, plasma, DNA.
Health parameters studied	Health event/morbidity
Procedures	
Participant monitoring	No
Links to administrative sources	No
Promotion and access	
Promotion	
Access	
Terms of data access (charter for data provision, format of data, availability delay)	Through publications. Contact the scientist in charge for further information.
Access to aggregated data	Access on specific project only
Access to individual data	Access on specific project only