

CIRRAL - Multicentric cohort of patients with compensated and non-complicated alcoholic cirrhosis, designed to study the incidence and predictors of hepatocellular carcinoma (HCC)

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General

Identification

Detailed name	Multicentric cohort of patients with compensated and non-complicated alcoholic cirrhosis, designed to study the incidence and predictors of hepatocellular carcinoma (HCC)
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Sign or acronym	CIRRAL
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CNIL registration number, number and date of CPP agreement, AFSSAPS (French Health Products Safety Agency) authorisation	Accord CNIL: 12/08/2010
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General Aspects

Medical area	Cancer research
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Health determinants	Addictions
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Others (details)	Cirrhosis, hepatocellular carcinoma
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Keywords	Alcohol, predictive factors
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Scientific investigator(s) (Contact)

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Unit	Hôpital Jean Verdier
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Organization	APHP
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Collaborations	
Funding	
Funding status	Mixed
Details	Institut national contre le Cancer, ANRS, ARC
Governance of the database	
Sponsor(s) or organisation(s) responsible	DRCD ILE DE FRANCE, APHP
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.	Prospective Inclusion cut-off date: April 2017 Number of required subjects: 1,200
Database objective	
Main objective	General objective: to describe the natural history of hepatocellular carcinoma (HCC) in alcoholic cirrhosis. Secondary objectives: - to establish a comparison with the national cohort - to establish a comparison with the national cohort of viral cirrhosis ANRS CO12 CirVir - to form an ancillary study database from biological resources taken at enrolment and afterwards annually as well as associated clinical data.
Inclusion criteria	Adult patients with compensated and non-complicated alcoholic cirrhosis at the time of enrolment.
Population type	

Age	Adulthood (19 to 24 years) Adulthood (25 to 44 years) Adulthood (45 to 64 years) Elderly (65 to 79 years)
Population covered	Sick population
Gender	Male Woman
Geography area	International
Detail of the geography area	Multicentric cohort throughout France and Belgium (24 centres).
Data collection	
Dates	
Date of first collection (YYYY or MM/YYYY)	10/2010
Size of the database	
Size of the database (number of individuals)	< 500 individuals
Details of the number of individuals	350 (01/05/2013) 1200 (2017)
Data	
Database activity	Current data collection
Type of data collected	Clinical data Declarative data Biological data
Clinical data (detail)	Direct physical measures Medical registration
Declarative data (detail)	Paper self-questionnaire Face to face interview
Biological data (detail)	NFS, platelets; bilirubin, AST, ALT, alkaline phosphatase, gamma-glutamyl transferase; albumin and gammaglobulin; prothrombin time, INR; creatinine, glucose, total cholesterol, triglycerides; serum iron, ferritin and coefficient of transferrin saturation; alpha-fetoprotein, characterisation of HIV coinfection as appropriate, date and result of oesophageal endoscopy, date and result of last liver

	ultrasound
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 Health care consumption and services
Care consumption (detail)	Medical/paramedical consultation
Procedures	
Data collection method	Clinical examinations: handwritten Biological analysis: handwritten
Participant monitoring	Yes
Details on monitoring of participants	Follow-up duration: minimum 3 years
Links to administrative sources	No
Promotion and access	
Promotion	
Access	
Terms of data access (charter for data provision, format of data, availability delay)	Data may be used by academic teams. Data may be used by industrial teams. Following review of projects by the scientific council and agreement thereof.
Access to aggregated data	Access on specific project only
Access to individual data	Access on specific project only