

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

Head :Ganne Nathalie, Hôpital Jean Verdier

Last update : 08/08/2014 | Version : 1 | ID : 60198

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)

Sign or acronym CIRRAL

CNIL registration number, number and date of CPP agreement, AFSSAPS (French Health Products Safety Agency) authorisation Accord CNIL: 12/08/2010

General Aspects

Medical area Cancer research

Health determinants Addictions

Others (details) Cirrhosis, hepatocellular carcinoma

Keywords Alcohol, predictive factors

Scientific investigator(s) (Contact)

Name of the director Ganne

Surname Nathalie

Address Avenue du 14 juillet, 93140 BONDY

Phone +33 (0)1 48 02 62 94

Email nathalie.ganne@jvr.aphp.fr

Unit Hôpital Jean Verdier

Organization APHP

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