## 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<br>and non-complicated alcoholic cirrhosis, designed<br>to study the incidence and predictors of<br>hepatocellular carcinoma (HCC) |  |
| Sign or acronym  | CIRRAL  |  |
| CNIL registration number,<br>number and date of CPP<br>agreement, AFSSAPS (French<br>Health Products Safety Agency)<br>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)<br>(Contact)  |   |  |
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| 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<br>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-<br>complicated alcoholic cirrhosis at the time of<br>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<br>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<br>Declarative data<br>Biological data   |
| Clinical data (detail)                       | Direct physical measures<br>Medical registration   |
| Declarative data (detail)                    | Paper self-questionnaire<br>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<br>Plasma<br>DNA   |
| Details of biobank content  | Serum bank, plasma bank, DNA bank  |
| Health parameters studied   | Health event/morbidity<br>Health event/mortality<br>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<br>for data provision, format of<br>data, availability delay) | Data may be used by academic teams. Data may<br>be used by industrial teams. Following review of<br>projects by the scientific council and agreement<br>thereof. |
| Access to aggregated data   | Access on specific project only  |
| Access to individual data   | Access on specific project only  |