

PRETHEVIC - Cohort of HIV/HCV Coinfected Patients with First Cirrhosis Decompensation or Hepatocellular Carcinoma

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General

Identification

Detailed name Cohort of HIV/HCV Coinfected Patients with First Cirrhosis Decompensation or Hepatocellular Carcinoma

Sign or acronym PRETHEVIC

CNIL registration number, number and date of CPP agreement, AFSSAPS (French Health Products Safety Agency) authorisation

CNIL

General Aspects

Medical area Cancer research
Gastroenterology et hepatology
Infectious diseases

Keywords HIV/HCV coinfection, prognostic survival factors, registration, transplant list, hepatic transplantation, liver transplantation

Scientific investigator(s) (Contact)

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Unit Centre Hépato-biliaire Paul Brousse

Organization Hôpital Paul

Collaborations

Funding

Funding status Public

Details -AP-HP - ANRS

Governance of the database

Sponsor(s) or organisation(s) responsible Centre hépato-biliaire Paul Brousse

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

Database objective

Main objective The main objective is to describe progress and treatment for HIV/HCV coinfecting individuals with first hepatic decompensation (HCC): frequency, type of hepatic decompensation, rate of liver function deterioration, percentage of patients that are included on the transplant list, percentage of patients that have had grafts, etc.

Inclusion criteria

- Aged 18 or over;
- Positive HIV serology;
- Positive HCV serology;
- Hepatic cirrhosis (histology/clinical? biological ? radiological evidence ? non-invasive methods)
- first episode of decompensation (ascites/gastrointestinal bleeding/hepatorenal syndrome/hepatic encephalopathy/ non-obstructive jaundice) OR HCC diagnosed less than a year ago.

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 National

Detail of the geography area 53 sites throughout France (île de France, Rennes, Brest, Nantes, Tourcoing, Nancy, Besançon, Dijon, Lyon, Grenoble, Aix, Nice, Marseilles, Montpellier, Toulouse, Bordeaux, Limoges and Tours).

Data collection

Dates

Date of first collection (YYYY or MM/YYYY) 05/2009

Date of last collection (YYYY or MM/YYYY) 05/2014

Size of the database

Size of the database (number of individuals) < 500 individuals

Details of the number of individuals 100

Data

Database activity Data collection completed

Type of data collected Clinical data
Paraclinical data
Biological data

Clinical data (detail) Direct physical measures

Details of collected clinical data Liver transplant.

Paraclinical data (detail) Radiology and endoscopy.

Biological data (detail) Anti-HVC antibodies, seropositive HIV.

Presence of a biobank Yes

Contents of biobank	Cell lines
Details of biobank content	Cell lines.
Health parameters studied	Health event/morbidity Health event/mortality Health care consumption and services
Care consumption (detail)	Hospitalization
Procedures	
Participant monitoring	Yes
Details on monitoring of participants	Quarterly collection of clinical, biological, radiological and endoscopic data will be carried out. A biobank will be established at baseline and then once a year.
Links to administrative sources	No
Promotion and access	
Promotion	
Link to the document	http://tinyurl.com/PUBMED-PRETHEVIC
Description	Liste des publications dans Pubmed
Access	
Terms of data access (charter for data provision, format of data, availability delay)	Contact the scientist in charge.
Access to aggregated data	Access on specific project only
Access to individual data	Access on specific project only