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

Head :Duclos Vallée Jean-Charles, Centre Hépato-biliaire Paul Brousse

Last update : 05/12/2015 | Version : 3 | ID : 8203

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)

Name of the director	Duclos Vallée
Surname	Jean-Charles
Address	12-14 avenue Paul Vaillant Couturier 94800 Villejuif
Phone	+33 (0)1 45 59 30 28
Email	jean-charles.duclos-vallee@pbr.aphp.fr
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 coinfected 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