

ANRS CO12 CIRVIR - Prospective cohort involving patients with viral cirrhosis B and C

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General

Identification

Detailed name	Prospective cohort involving patients with viral cirrhosis B and C
Sign or acronym	ANRS CO12 CIRVIR
CNIL registration number, number and date of CPP agreement, AFSSAPS (French Health Products Safety Agency) authorisation	CPP : PC/AP 11-2005 (15.06.2012), CNIL : 90.54.63 (19.01.2006), CCTIRS : 05.394 (01.09.2005)

General Aspects

Medical area	Gastroenterology et hepatology
Health determinants	Lifestyle and behavior
Keywords	Cirrhosis related HCV and/or HBV, HCC, predictive factors, prognostic factors

Scientific investigator(s) (Contact)

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Organization	APHP-Inserm

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Unit	Service de santé publique, Hôpital Henri Mondor
Organization	APHP
Collaborations	
Participation in projects, networks and consortia	Yes
Funding	
Funding status	Public
Details	Agence Nationale de Recherche sur le Sida et les hépatites Virales (ANRS - agence autonome de l'Inserm)
Governance of the database	
Sponsor(s) or organisation(s) responsible	Agence Nationale de Recherches sur le SIDA et les Hépatites Virales (ANRS) Public
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 - Closing date for inclusion not determined

Database objective	
Main objective	Description of the natural history of HBV and/or HCV compensated cirrhosis.
Inclusion criteria	1. Presence of a histologically proven cirrhosis (metavir F4 or established cirrhosis) 2. No prior episode, not on the day of inclusion, decompensation or CHC 3. Presence of a laboratory evidence of infection with the hepatitis B and/or hepatitis C virus Note: HIV coinfections are eligible.
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	National
Detail of the geography area	38 centers in France
Data collection	
Dates	
Date of first collection (YYYY or MM/YYYY)	03/2006
Size of the database	
Size of the database (number of individuals)	[1000-10 000[individuals
Details of the number of individuals	2000
Data	
Database activity	Current data collection
Type of data collected	Clinical data Paraclinical data Biological data

Clinical data (detail)	Medical registration
Biological data (detail)	CBC-platelets, TP, factor V, normal liver chemistry (ASAT, ALAT, PA, GGT), total bilirubin, albumin, alpha fetoprotein
Presence of a biobank	Yes
Contents of biobank	Serum Plasma DNA
Details of biobank content	Serum bank, plasma bank, cell bank
Health parameters studied	Health event/morbidity Health event/mortality
Procedures	
Participant monitoring	Yes
Details on monitoring of participants	Half-year follow-up (according to HAS recommendations) in terms of clinical examination, biological balance and imagery examination
Links to administrative sources	No
Promotion and access	
Promotion	
Link to the document	http://www.hal.inserm.fr/CO12_CIRVIR
Description	List of publications in HAL
Link to the document	http://www.ncbi.nlm.nih.gov/pubmed/?term=CO12+Cirvir
Description	List of publications in Pubmed
Access	
Terms of data access (charter for data provision, format of data, availability delay)	Methods of distribution: BEH Request placed with the Investigator-coordinator
Access to aggregated data	Access on specific project only
Access to individual data	Access on specific project only