ANRS C013 HEPAVIH - Inter-cohort and clinical centers collaboration of subjects co-infected by human immunodeficiency virus and hepatitis C

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Last update : 08/07/2019 | Version : 3 | ID : 3626

General

Identification

Detailed name	Inter-cohort and clinical centers collaboration of subjects co-infected by human immunodeficiency virus and hepatitis C
Sign or acronym	ANRS C013 HEPAVIH
CNIL registration number, number and date of CPP agreement, AFSSAPS (French Health Products Safety Agency) authorisation	ClinicalTrials : NCT03324633 ; CPP : CG/LG/CC 2005-466

General Aspects

Medical area	Immunology Infectious diseases
Health determinants	Lifestyle and behavior
Keywords	Adults, disease carriers, cured, treatment, co-infection

Scientific investigator(s) (Contact)

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Organization	Assistance Publique des Hôpitaux de Paris - Hôpitaux Paris Centre, Université Paris Descarte, Inserm

Collaborations

Participation in projects, networks and consortia	Yes

Funding

Funding status	Mixed
Details	ANRS, INSERM, Laboratoires Glaxo-SmithKline, Roche, Schering Plough et Janssen

Governance of the database

Sponsor(s) or organisation(s) responsible	ANRS - AGENCE NATIONALE DE RECHERCHES SUR LE SIDA ET LES HEPATITES VIRALES
Organisation status	Public
Presence of scientific or steering committees	Yes

Additional contact

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Organization	ANRS

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.	Dates and inclusions duration: Phase 1: 2005-2008 (3 years) Phase 2: 2011-2014 (3 years)

Database objective

Main objective	Short term: - Describe patient's characteristics - Analyze factors associated to a treatment of hepatitis C: beginning of the treatment, continuation or stop of the treatment. - Validate the field performance of not-invasive markers of hepatic fibrosis. Mid-term: - Realize an observational study of the evolution of hepatitis during an anti-VHC treatment, in an antiviral situation - Study the clinical and biological tolerance to the different treatments. - Study the impact of the observance of the treatment anti HIV and the life quality of patients. Long term: Study the natural history of chronic hepatitis, in particular at the stage of cirrhosis. - Analyze the factors associated to the evolution to fibrosis, to a decompensated hepatic disease or an hepatocellular carcinoma. - Evaluate the effects of antiretroviral agents on the evolution of not-treated hepatitis - Study the potential interactions between different virus of hepatitis
Inclusion criteria	Adults infected by HIV virus carriers of VHC or cured after anti-VHC treatment, or spontaneously healed without anti-VHC treatment or benefiting from an anti-VHC tritherapies.

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
Pathology	B24 - Unspecified human immunodeficiency virus [HIV] disease
	B15-B19 - Viral hepatitis
Gender	Male Woman Other
Geography area	National
Detail of the geography area	French multi-centers cohort (28 centers)

Data collection

Dates

Date of first collection (YYYY or MM/YYYY)	01/2006
Date of last collection (YYYY or MM/YYYY)	09/2022

Size of the database

Size of the database (number of individuals)	[1000-10 000[individuals
Details of the number of individuals	1849 in june 2018

Data

Database activity	Current data collection
Type of data collected	Clinical data Declarative data Paraclinical data Biological data
Clinical data (detail)	Direct physical measures Medical registration
Details of collected clinical data	Clinical examination at inclusion and during the follow-up. Information collected during the clinical examination: weigh, height, waist and hips circumference
Declarative data (detail)	Paper self-questionnaire Face to face interview

Details of collected declarative data	Clinical examination at inclusion and during the follow-up. Information collected during the clinical examination: weigh, height, waist and hips circumference
Paraclinical data (detail)	Radiology, evaluation of the hepatic fibrosis
Biological data (detail)	Blood check
Presence of a biobank	Yes
Contents of biobank	Whole blood Serum Plasma
Details of biobank content	Serum bank, plasma bank, DNA bank, total blood, tissues bank in a non-systematic way
Health parameters studied	Health care consumption and services Quality of life/health perception
Care consumption (detail)	Medical/paramedical consultation Medicines consumption

Procedures

Data collection method	Self-questionnaire: filled from a paper questionnaire. Interviews: filled from a paper questionnaire .Clinical examination: manual data entry .Biological examination: manual data entry
Classifications used	---
Quality procedure(s) used	Data utilization possible for academic teams and for industrials. Temporary access condition : project accepted by the scientific committee
Participant monitoring	Yes
Monitoring procedures	Monitoring by contact with the referring doctor
Details on monitoring of participants	Annual or bi-annual, specific according to the anti-VHC treatment
Links to administrative sources	No

Promotion and access

Promotion

Link to the document	Liste publications COHORTE ANRS CO13 HEPAVIH 20180830.pdf

Description	List of publications in HAL
Link to the document	http://www.ncbi.nlm.nih.gov/pubmed/?term=HEPAVIH+OR+ANRS+CO13+OR+%28cohere+AND+%28hiv+OR+AIDS%29%29
Description	List of publications in Pubmed

Access	
Presence of document that lists variables and coding procedures	Yes
Terms of data access (charter for data provision, format of data, availability delay)	Data utilization possible for academic teams and for industrials. Temporary access condition : project accepted by the scientific committee
Access to aggregated data	Access on specific project only
Access to individual data	Access on specific project only