

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

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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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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	<p>Short term:</p> <ul style="list-style-type: none"> - 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. <p>Mid-term:</p> <ul style="list-style-type: none"> - 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. <p>Long term:</p> <p>Study the natural history of chronic hepatitis, in particular at the stage of cirrhosis.</p> <ul style="list-style-type: none"> - 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
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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.
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Population type

Age	<p>Adulthood (19 to 24 years)</p> <p>Adulthood (25 to 44 years)</p> <p>Adulthood (45 to 64 years)</p> <p>Elderly (65 to 79 years)</p>
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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+%28coherence+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