

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

Head :Wittkop Linda, INSERM, U1219, Centre de Recherche Inserm Bordeaux Publique Health, équipe Morpheus, CMG-EC
Salmon Dominique, Services des Maladies Infectieuses et Tropicales
Sogni Philippe, Service d'Hépatologie

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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)	
Name of the director	Wittkop
Surname	Linda
Address	VIH, Hépatites Virales et comorbidités : épidémiologie clinique et santé publique / Multimorbidity and Public Health in Patients with HIV or Hepatitis (MORPH3Eus) CMG-EC de l'INSERM U1219 / ANRS Université de Bordeaux ISPED 146, rue Léo Saignat ? CS61292

33076 Bordeaux cedex
FRANCE

Phone +33 (0)5 57 57 13 92

Email linda.wittkop@u-bordeaux.fr

Unit INSERM, U1219, Centre de Recherche Inserm
Bordeaux Publique Health, équipe Morpheus, CMG-
EC

Organization Inserm

Name of the director Salmon

Surname Dominique

Phone +33 (0) 1 42 34 79 56

Email dominique.salmon@aphp.fr

Unit Services des Maladies Infectieuses et Tropicales

Organization Assistance Publique des Hôpitaux de Paris -
Hôpitaux Paris Centre, Université Paris Descartes

Name of the director Sogni

Surname Philippe

Address Hôpital Cochin

Email philippe.sogni@aphp.fr

Unit Service d'Hépatologie

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	
Name of the contact	Esterle
Surname	Laure
Address	VIH, Hépatites Virales et comorbidités : épidémiologie clinique et santé publique / Multimorbidity and Public Health in Patients with HIV or Hepatitis (MORPH3Eus) CMG-EC de l'INSERM U1219 / ANRS Université de Bordeaux ISPED 146, rue Léo Saignat ? CS61292 33076 Bordeaux cedex FRANCE
Phone	+(33)5 57 57 92 71
Email	laure.esterle@u-bordeaux.fr
Unit	INSERM, U1219, Centre de Recherche Inserm Bordeaux Public Health, équipe Morpheus, CMG- EC
Organization	Inserm
Name of the contact	ANRS
Address	101 rue de Tolbiac 75013 Paris
Unit	Service de recherches fondamentales, cliniques et thérapeutiques sur les Hépatites virales
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
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	<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>

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