ANRS C05 VIH-2 - Natural History of HIV-2-infected Adult Patients Living In France

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General

Identification

Detailed name	Natural History of HIV-2-infected Adult Patients Living In France
Sign or acronym	ANRS C05 VIH-2
CNIL registration number, number and date of CPP agreement, AFSSAPS (French Health Products Safety Agency) authorisation	Accord CNIL: 04/02/2003

General Aspects

Medical area	Infectious diseases
Study in connection with Covid-19	No
Pathology (details)	HIV-2
Health determinants	Addictions Geography Healthcare system and access to health care services Iatrogenic Lifestyle and behavior Social and psychosocial factors
Keywords	HIV; HIV-2; natural history; AIDS

Scientific investigator(s) (Contact)

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Organization	APHP

Collaborations

Participation in projects, networks and consortia	Yes
Details	cohort network: ACHIEV2E (network of 14 European and 2 West African centers),
Others	Immunovir-2 consortium

Funding

Funding status	Public
Details	INSERM-ANRS

Governance of the database

Sponsor(s) or organisation(s) responsible	Agence Nationale de Recherches sur le Sida et les hépatites virales (ANRS)
Organisation status	Public
Presence of scientific or steering committees	Yes

Additional contact

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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.	National Multicentric Open Prospective observational cohort, Inclusion end date: 30 September 2021

Database objective

Main objective	Main objective To study HIV-2 infection in adult patients followed in France. Secondary objectives - To describe the epidemiological and clinical characteristics of participants infected with HIV-2, and the immuno-virological characteristics of the infection. - To study the clinical and immunological progression of HIV-2 infection and the prognostic factors for this progression. - To study the response (clinical, immuno-virological) to antiretroviral treatment and to contribute to the identification of antiretroviral strategies and combinations best suited to the particularities of the

	infection. - To allow an evaluation of the management practices of the participants - To provide a clinical and biological database and samples for basic science studies on HIV-2 infection.
Inclusion criteria	Inclusion Criteria : - HIV-2 infection only, diagnosed by ELISA, confirmed by Western-Blot, - Follow-up in one of the investigator centers, - Age greater than or equal to 18 years, - Extended follow-up possible, residence in France planned for at least one year, - Participant's consent to participate, - Possible ALD (Long Term Disorder) status for the participant, or state medical aid (SMA), or declaration of obtaining SMA at the time of inclusion. Criteria for non-inclusion : - HIV-1 infection - double HIV-1 + HIV-2 seropositivity. Translated with www.DeepL.com/Translator (free version)

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
Pathology	I - Certain infectious and parasitic diseases
Gender	Male Woman
Geography area	National
Detail of the geography area	French Multicentric cohort (117 centres until 30/10/2019 then 34 centres)

Data collection

Dates

Date of first collection (YYYY or	1994

MM/YYYY)	
Date of last collection (YYYY or MM/YYYY)	ongoing
Size of the database	
Size of the database (number of individuals)	[1000-10 000[individuals
Details of the number of individuals	1185 participants, 540 under follow-up
Data	
Database activity	Current data collection
Type of data collected	Clinical data Declarative data Biological data Administrative data
Clinical data (detail)	Direct physical measures Medical registration
Details of collected clinical data	Clinical examination at baseline and at 6-month follow-up; information collected during clinical examination: weight, blood pressure, CDC stage B or C events, other clinical events, and, for women, pregnancy and menopause.
Declarative data (detail)	Face to face interview
Details of collected declarative data	socio-demographic data, data on diagnosis and circumstances of HIV-2 infection, medical history, drug use, pregnancy(ies), antiretroviral treatment, clinical and biological data.
Biological data (detail)	Blood sample
Administrative data (detail)	nationality
Presence of a biobank	Yes
Contents of biobank	Serum Plasma Blood cells isolated Others
Details of biobank content	plasma bank (/6 months), serum bank and cell bank (/12 months)
Health parameters studied	Health event/morbidity

	Health event/mortality
Procedures	
Data collection method	Interview: input from a paper questionnaire with double data entry Clinical examinations: handwritten with double data entry Biological analysis: handwritten with double data entry
Quality procedure(s) used	Consistency checks after data entry. Remote and on-site monitoring: return to the source folder for data management and verification. Patients are informed about the use of their data.
Participant monitoring	Yes
Monitoring procedures	Monitoring by convocation of the participant Monitoring by crossing with a medical-administrative database
Details on monitoring of participants	Visit (clinical examination and blood sample); asymptomatic patients: every 6 months. Antiretroviral treated-patients, 1 month after treatment initiation, then every 3 months, then every 3 or 6 months depending on immunovirological status and adherence. Additional visit in case of intermediate event (start or change of antiretroviral treatment, clinical progression, pregnancy)
Followed pathology	I - Certain infectious and parasitic diseases
Links to administrative sources	No
Promotion and access	
Promotion	
Link to the document	http://tinyurl.com/Hal-ANRS-CO5-HIV-2
Description	List of publications in HAL
Link to the document	http://www.ncbi.nlm.nih.gov/pubmed/?term=Anrs+AND+%28CO5+OR+%28HIV-2+AND+CO+05%29%29
Description	List of publications in Pubmed
Access	
Dedicated website	http://www.anrs.fr/index.php/anrs/vih_sida/clinique/repertoire_des_etudes_cliniques

Terms of data access (charter for data provision, format of data, availability delay)	Possible use of the data by academic teams Time access requirements for academic research (collaborations for virological and immunological satellite studies, and therapeutic trials) Possible use of the data by industrialists Conditions of access possible industrial contractual collaborations (ANRS)
Access to aggregated data	Access on specific project only
Access to individual data	Access on specific project only