

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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Organization	INSERM / 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. 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.

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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/HaI-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