ANRS CO6 PRIMO - Primary infection cohort

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General

Identification

Detailed name	Primary infection cohort
Sign or acronym	ANRS CO6 PRIMO
CNIL registration number, number and date of CPP agreement, AFSSAPS (French Health Products Safety Agency) authorisation	CNIL n° 997056 du 15/09/1997 ; CPP n°1157, avis favorable le 02/07/1996 ; DGS : n° 960695 le 06/03/1997

General Aspects

Medical area	Biology Infectious diseases
Health determinants	Geography Social and psychosocial factors
Keywords	Heath events, serious pathologies, lipodystrophies, death

Scientific investigator(s) (Contact)

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Organization	APHP

Collaborations

Participation in projects, networks and consortia	Yes

Funding

Funding status	Public
Details	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
Sponsor(s) or organisation(s) responsible	INSERM
Organisation status	Public

Additional contact

Main features

Type of database

Additional information regarding sample selection.	Type of enrollment: prospective End of enrollment : 31 December 2015

Database objective

Main objective	Follow up of patients infected by HIV-1 for less than three months. 1. Improve the pathophysiological l knowledge of primary HIV infection - Study of the immune mechanisms involved early after infection - Kinetics of viral replication and establishment of cellular reservoirs at an early stage - Relationships between virological markers and immune response kinetics - Impact of resistance mutations, subtype and tropism on the disease progression and the response to treatment - Study of sub-groups of specific patients followed since primary infection, spontaneous or post treatment controllers, subjects with particular HLA 2. Assessing the impact of early, transient or prolonged treatment versus deferred treatment on the long-term prognosis of patients followed since primary infection, in terms of activation / inflammation and decrease in viral reservoirs 3. Contribute to knowledge in the epidemiology of HIV infection: - Modes of transmission - Sexual behavior before and after HIV diagnosis - Calendar trend of transmitted viral strains diversity (ARV resistance and subtypes) - Calendar trend of marker levels measured at primary infection 4. Contribute to national recommendations for therapeutic care, evaluate their implementation 5. Use observational data from the cohort for the development of therapeutic clinical trials in primary infection
Inclusion criteria	1) symptomatic or asymptomatic HIV-1 primary infection. 2) Infection date based on one of the following criteria: incomplete Western Blot; or positive p24 antigenemia/detectable plasma HIV RNA along with a negative or weakly positive ELISA or a negative or undetermined Western Blot, or a negative ELISA within the three previous months. 3) Enrollment within a maximum of 3 months after the estimated infection date. 4) Naive of antiretroviral treatment except for transient treatment taken in the context of PMTCT, PrEP or PEP.

Population type

Age	Adulthood (19 to 24 years) Adulthood (25 to 44 years) Adulthood (45 to 64 years)
Population covered	Sick population
Gender	Male Woman
Geography area	National
Detail of the geography area	open, prospective, multicenter (94 centers) cohort

Data collection

Dates

Date of first collection (YYYY or MM/YYYY)	11/1996
Date of last collection (YYYY or MM/YYYY)	2020

Size of the database

Size of the database (number of individuals)	[1000-10 000[individuals
Details of the number of individuals	1625 in January 2013

Data

Database activity	Current data collection
Type of data collected	Clinical data Declarative data Biological data
Clinical data (detail)	Direct physical measures Medical registration
Declarative data (detail)	Paper self-questionnaire
Biological data (detail)	Blood samples
Presence of a biobank	Yes
Contents of biobank	Whole blood Serum Plasma Fluids (saliva, urine, amniotic fluid, ?)

Details of biobank content	Plasma, Lymph, cells, and total blood
Health parameters studied	Health event/morbidity Health event/mortality Health care consumption and services
Care consumption (detail)	Medicines consumption

Procedures

Data collection method	Self administered questionnaires: data entered from a questionnaire filled out by the patient by hand Clinical examination: written crf Biological exams: written crf
Participant monitoring	Yes
Details on monitoring of participants	Visits, clinical CRF and blood samples at baseline, M1, M3, M6 and then every 6 months. Possible enrollment in one of these additional modules: - Immunology Module: Additional samples for immunological investigations. - Clinical trial module: possible enrollment in a clinical trial. - Partner module: collection of the partner's blood sample at the time of patient enrollment in the cohort in order to perform specific analysis and record information on their health status. - Spontaneous and post-treatment control modules: additional blood samples for immunological and virological investigations during the control period
Links to administrative sources	Yes

Promotion and access

Promotion

Access

Terms of data access (charter for data provision, format of data, availability delay)	data available to academic teams
Access to aggregated data	Access on specific project only
Access to individual data	Access on specific project only