ANRS CO14 IL-2 - Cohort of HIV-Infected Patients Treated with Interleukin-2 (IL-2). Study of Tolerance and Long-Term Clinical and Biological Progression of Immunotherapy Treatment.

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General

Identification

Detailed name	Cohort of HIV-Infected Patients Treated with Interleukin-2 (IL-2). Study of Tolerance and Long-Term Clinical and Biological Progression of Immunotherapy Treatment.
Sign or acronym	ANRS CO14 IL-2
CNIL registration number, number and date of CPP agreement, AFSSAPS (French Health Products Safety Agency) authorisation	Ethical Research Committee: favourable opinion dated 03/03/2006, no. 06-001 and AFSSAPS: declaration no. 060353

General Aspects

Medical area	Immunology Infectious diseases
Keywords	Neoplasia, autoimmune disease, systemic, specific, clinical progression, immunovirology, cardiovascular events

Scientific investigator(s) (Contact)

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Organization	IMRB (Institut Mondor de Recherche
Collaborations	
Others	Other associated cohorts: French hospital database (FHDH) on HIV infection.
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
Additional contact	
Main features	
Type of database	
Type of database	Study databases
Study databases (details)	Cohort study

Database recruitment is carried out by an intermediary	An administrative base or a register
Database recruitment is is made on the basis of:	Medication(s) taken
Additional information regarding sample selection.	Prospective Inclusion cut-off date: 01/01/2010 Other bodies active in creating this cohort: INSERM U270

Database objective

Main objective	General objective: to study the long-term clinical tolerance of IL-2 treatment administered to patients infected with HIV. In particular, to monitor the occurrence of non-Hodgkin's lymphoma, neoplasia, systematic or specific autoimmune diseases and cardiovascular events, including venous or arterial thrombosis. Secondary objective: to investigate clinical progression (occurrence of events related to HIV and AIDS classification) and biological progression (CD4 and CD8 immune response and viral load) of HIV infection.
Inclusion criteria	HIV-infected individuals over 18 years of age that have received at least one course of IL-2 in the ANRS trial or authorisation for temporary use, who have given signed consent and are affiliated members or beneficiaries of a social security scheme.

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
Gender	Male Woman
Geography area	National
Detail of the geography area	Multicentric cohort throughout France (20 centres)

Data collection

Dates

Date of first collection (YYYY or	01/2007

MM/YYYY)

Size of the database	
Size of the database (number of individuals)	[500-1000[individuals
Details of the number of individuals	613 Number of required subjects : [500-1000]

Data	
Database activity	Current data collection
Type of data collected	Clinical data Paraclinical data Biological data
Clinical data (detail)	Direct physical measures Medical registration
Details of collected clinical data	Clinical examination at baseline and during follow-up. Frequency of examination: 4 years Information collected during clinical examination: IL2 tolerance, clinical and immuno-virological monitoring of HIV infection.
Paraclinical data (detail)	Anthropomorphic data (lipodystrophy)
Biological data (detail)	Type of samples taken: Blood
Presence of a biobank	Yes
Contents of biobank	Whole blood Serum Plasma
Details of biobank content	Biobank: Serum Bank, plasma bank, whole blood
Health parameters studied	Health event/morbidity Health event/mortality

Procedures	
Data collection method	Clinical examination: manual input
Quality procedure(s) used	Request for consistency after data is processed electronically Missing data is managed by returning to source file or third party
Participant monitoring	Yes

Details on monitoring of participants	Follow-up duration: 3 years, monitoring until 30th June 2013, modified in accordance with protocol amendment
Links to administrative sources	No

Promotion and access

Promotion

Access

Terms of data access (charter for data provision, format of data, availability delay)	Data may be used by academic teams Access in accordance with agreement from sponsor and Scientific Council Data may be used by industrial teams Access in accordance with agreement from sponsor, their Board of Directors and the cohort Scientific Council under contract.
Access to aggregated data	Access on specific project only
Access to individual data	Access on specific project only