

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.
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Funding

Funding status	Public
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Details	ANRS
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Governance of the database

Sponsor(s) or organisation(s) responsible	Agence Nationale de Recherches sur le Sida et les hépatites virales (ANRS)
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Organisation status	Public
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Additional contact

Main features

Type of database

Type of database	Study databases
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Study databases (details)	Cohort study
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Database recruitment is carried out by an intermediary An administrative base or a register

Database recruitment 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 YYYYMM) 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