

# 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.

Head :Costagliola Dominique, INSERM U720

ABOULKER Jean-Pierre, INSERM SC10 jp.aboulker@vjf.inserm.fr

LEVY Yves, Inserm U955

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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)

Name of the director Costagliola

Surname Dominique

Address BP 335 75625 Paris cedex 13

Phone +33(0)1 42 16 42 82

Email dcostagliola@ccde.chups.jussieu.fr

Unit INSERM U720

Name of the director ABOULKER

Surname	Jean-Pierre
Address	16 av. Paul Vaillant Couturier, 94708 Villejuif Cedex
Phone	+33 (0)1 45 59 51 72 ou +33 (0)1 45 59 51 13
Email	jean-pierre.aboulker@inserm.fr
Unit	INSERM SC10 jp.aboulker@vjf.inserm.fr

Name of the director	LEVY
Surname	Yves
Address	8 rue du général Sarrail, 94011 Créteil
Phone	+33 (0)1 49 81 36 93
Email	yves.levy@hmn.ap-hop-paris.fr
Unit	Inserm U955
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