ANRS CO9 COPANA - Cohort of HIV-Infected Patients with No Antiretroviral Treatment At Baseline

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General

Identification

Detailed name	Cohort of HIV-Infected Patients with No Antiretroviral Treatment At Baseline
Sign or acronym	ANRS CO9 COPANA
CNIL registration number, number and date of CPP agreement, AFSSAPS (French Health Products Safety Agency) authorisation	CNIL no. 04-1388 (08/09/2004), CPP no. 2087 (08/07/2003), DGS no. 2003/0455.

General Aspects

Medical area	Biology Infectious diseases
Health determinants	Genetic
Keywords	living conditions, mortality, health event, metabolic disorders, fat distribution disorders, treatment response

Scientific investigator(s) (Contact)

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Collaborations

Funding

Funding status	Public
Details	ANRS

Governance of the database

Sponsor(s) or organisation(s) responsible	Agence Nationale de Recherche 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	A selection of health institutions and services
Database recruitment is is made on the basis of:	Medication(s) taken
Database recruitment is carried out as part of an interventional study	No
Additional information regarding sample selection.	Prospective. Inclusion cut-off datet: 01/01/2008.

Database objective

Main objective	Main objective: To study the short-, medium- and long-term prognosis for newly diagnosed HIV patients. To investigate HIV-related clinical events, unexpected diseases, neoplastic diseases and long-term immuno-virological progression; to investigate the impact of HIV treatment on morbidity and mortality, factors associated with treatment response, clinical and biological complications, consequences, especially lipodystrophy and metabolic abnormalities, associated factors, including genetic factors; long-term therapeutic adherence, particularly the frequency and impact of treatment interruptions; to investigate the development in living conditions and behaviour of recently diagnosed patients, particularly regarding sexuality, reproduction, and health inequalities.
Inclusion criteria	Patients infected with HIV-1 with recent seropositive diagnosis (less than 1 year) and untreated at enrolment - age 15 or over and agreeing to participate in the cohort. One third of the patients were included in the TM module (metabolic disorders). This module includes additional biological and imaging examinations.

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	Multcentric French cohort (37 centres).
Data collection	
Dates	
Date of first collection (YYYY or MM/YYYY)	01/2004
Size of the database	
Size of the database (number of individuals)	[500-1000[individuals
Details of the number of individuals	800
Data	
Database activity	Data collection completed
Type of data collected	Clinical data Declarative data Paraclinical data Biological data
Clinical data (detail)	Direct physical measures Medical registration
Details of collected clinical data	Clinical examination at baseline and every two years during follow-up. Information collected during clinical examination: clinical examination includes physician screening and monitoring of fat distribution abnormalities.
Declarative data (detail)	Paper self-questionnaire
Details of collected declarative data	Self-administered questionnaire at baseline and during follow-up every year. Information collected by self-administered questionnaire: food consumption, physical activity, smoking, self-evaluation of morphological disorders and living conditions.
Paraclinical data (detail)	Imaging.
Biological data (detail)	Blood sample.

Presence of a biobank	Yes
Contents of biobank	Whole blood Serum Plasma Fluids (saliva, urine, amniotic fluid, ?)
Details of biobank content	Serum bank, plasma bank, lymph bank and whole 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 questionnaire: input from a paper questionnaire. Clinical examinations: handwritten. Biological analysis: handwritten.
Quality procedure(s) used	Consistency request after electronic data is recorded. Missing data is managed by returning to source record. Physician reminder for follow-up visits. Patients are informed about the use of their data.
Participant monitoring	Yes
Details on monitoring of participants	Visit every 6 months for 10 years.
Links to administrative sources	No

Promotion and access

Promotion

Link to the document	http://www.hal.inserm.fr/ANRSCO9
Description	List of publications in HAL
Link to the document	http://www.ncbi.nlm.nih.gov/pubmed/?term=%28Copana+AND+Anrs%29+OR+ANRS+CO9
Description	List of publications in Pubmed

Access

Terms of data access (charter	Data can be used by academic teams.

for data provision, format of data, availability delay)	
Access to aggregated data	Access on specific project only
Access to individual data	Access on specific project only