

PRELUDE - Study of factors affecting the lives of people treated by anti-HIV drugs in long term - FRAN09-014

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General

Identification

Detailed name Study of factors affecting the lives of people treated by anti-HIV drugs in long term - FRAN09-014

Sign or acronym PRELUDE

CNIL registration number, number and date of CPP agreement, AFSSAPS (French Health Products Safety Agency) authorisation

909498

General Aspects

Medical area Infectious diseases
Psychology and psychiatry

Health determinants Addictions
Social and psychosocial factors

Keywords anti-retroviral drugs (ARV) in the long term, factors: daily life, professional life, social life

Scientific investigator(s) (Contact)

Name of the director Cohen-Codar

Surname Isabelle

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Organization ABBVIE

Collaborations

Funding

Funding status Private

Details	ABBOTT France
Governance of the database	
Sponsor(s) or organisation(s) responsible	ABBOTT France
Organisation status	Private
Sponsor(s) or organisation(s) responsible	Abbott
Organisation status	Private
Additional contact	
Main features	
Type of database	
Type of database	Study databases
Study databases (details)	Not-repeated cross-sectional studies (except case control studies)
Database recruitment is carried out by an intermediary	A selection of health institutions and services
Database recruitment 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.	"Random selection of doctors from the database of doctors working on HIV and listed in the file of the French Medical Board. Patients examined in consultation having the selection criteria and accepting to participate in this study. Each doctor could include 15 patients examined in consultation and meeting the selection criteria."
Database objective	
Main objective	Describe the factors affecting the life of individuals treated in the long term by anti-HIV drugs. Describe the factors affecting the life of individuals treated in the long term by anti-HIV drugs according to their age. Evaluate the correlation between the age, duration of seropositivity, the duration under treatment and the disorders reported.

Compare the patient's view and that of his doctor concerning the factors described in the main objective.

Inclusion criteria

* HIV-infected patients, treated with antiretroviral agents for at least 5 years and examined in consultation in their normal care center for monitoring their infection
* Obtaining written consent for the collection and use of personal data

Population type

Age

Adulthood (19 to 24 years)
Adulthood (25 to 44 years)
Adulthood (45 to 64 years)
Elderly (65 to 79 years)

Population covered

Sick population

Gender

Male
Woman

Geography area

National

Detail of the geography area

Metropolitan France and Overseas
Départements/Territories

Data collection

Dates

Date of first collection (YYYY or MM/YYYY)

04/2010

Date of last collection (YYYY or MM/YYYY)

07/2010

Size of the database

Size of the database (number of individuals)

[1000-10 000[individuals

Details of the number of individuals

1157

Data

Database activity

Data collection completed

Type of data collected

Clinical data
Declarative data

Clinical data (detail)	Direct physical measures Medical registration
Declarative data (detail)	Paper self-questionnaire Face to face interview
Presence of a biobank	No
Health parameters studied	Health event/morbidity Health care consumption and services Quality of life/health perception
Care consumption (detail)	Medicines consumption

Procedures

Data collection method	The data was collected using the doctor's questionnaire and the patient's self-questionnaire.
Participant monitoring	No
Links to administrative sources	No

Promotion and access

Promotion

Access

Terms of data access (charter for data provision, format of data, availability delay)	Analysis of the data of the study in progress.
Access to aggregated data	Access on specific project only
Access to individual data	Access on specific project only