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

Head :Cohen-Codar Isabelle

Last update : 07/01/2020 | Version : 3 | ID : 113

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
Address	10, rue d'Arcueil ? 94258 RUNGIS
Email	Isabelle.Cohen-Codar@abbvie.com
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 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