BINOME - Observational study of the sociodemographic characteristics of patients infected with HIV B subtype versus HIV non-B subtype and having recently started their first course of antiretroviral treatment.

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General

Identification

Detailed name	Observational study of the sociodemographic characteristics of patients infected with HIV B subtype versus HIV non-B subtype and having recently started their first course of antiretroviral treatment.
Sign or acronym	BINOME
CNIL registration number, number and date of CPP agreement, AFSSAPS (French Health Products Safety Agency) authorisation	CNIL n°906292

General Aspects

Medical area	Infectious diseases
Health determinants	Occupation Social and psychosocial factors
Keywords	anti-retroviral drug treatment (ARV), viral subtype, Protease inhibitors (PI), non-nucleoside reverse transcriptase inhibitors (NNRTI), HIV

Scientific investigator(s) (Contact)

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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
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.Each physician accepting to participate in the study will include the first 4 consecutive patients examined in consultation and meeting the eligibility criteria of which 2 patients in group 1 and 2 patients in group 2.
Database objective	
Main objective	Describe and compare the socio-demographic characteristics of patients infected with an HIV-1 of subtype B (group 1) compared to non-B (group 2) treated with a first anti-retroviral drug treatment. Compare according to the HIV subtype the stage of the disease (clinical, viro-immunology, co-morbidities) at the time treatment is initiated, compare between the 2 groups (B and non-B) the

	conditions for taking the treatment and the perception by the patient of the therapy and of its effects. Identification of any correlation between these latter parameters and the change in the disease between the initiation and the first line ARV and the inclusion in the cohort: - change in the viral load (VL) according to the ARV treatment (PI, NNRTI) and of the HIV subtype (B or non-B), of the CD4, - any occurrence of clinical events, - any changes in treatments and reasons.
Inclusion criteria	Age > 18 years, obtaining of written consent for the collection of this personal data, patient infected by the HIV-1 virus, patient coming to consult for the first or second routine follow-up visit (i.e. 1 to 4 months) after the initiation of the ARV treatment, genotype available when the treatment is initiated.
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
Data collection	
Dates	
Date of first collection (YYYY or MM/YYYY)	04/2007
Date of last collection (YYYY or MM/YYYY)	07/2008
Size of the database	
Size of the database (number of individuals)	< 500 individuals
Details of the number of individuals	304

Data	
Database activity	Data collection completed
Type of data collected	Clinical data Declarative data Biological data
Clinical data (detail)	Direct physical measures Medical registration
Declarative data (detail)	Paper self-questionnaire Face to face interview
Biological data (detail)	biological monitoring of the HIV infection
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	"Patient" observation sheets completed by the physician and sent by the post to the company in charge of data management. Visual analog scales completed by the patient and remitted to the physician and then sent to the company in charge of data management.
Participant monitoring	No
Links to administrative sources	No
Promotion and access	
Promotion	
Link to the document	http://www.ncbi.nlm.nih.gov/pubmed/21233637
Access	
Terms of data access (charter for data provision, format of data, availability delay)	Methods for accessing the raw data are currently being defined. Distribution of the results of the study: (see the tab for more information) Poster: O. Bouchaud, V. Le Moing, F. Simon, P. NgoVan, P.

	Perre, L. Hocqueloux, B. Lebouche, S. Carret, B. Spire, Subjects infected with B versus non-B HIV 1 Subtypes in France: Differences in Social and demographic Conditions, but Similar Short-term virological Outcome on Therapy, 16th Conference on Retroviruses and Opportunistic Infection (CROI 2009), Montreal, Canada, 8-11 Feb 2009. Article: O. Bouchaud, V. Le Moing, F. Simon, P. NgoVan, P. Perre, L. Hocqueloux, B. Lebouche, S. Carret, B. Spire, Similar Short-Term Efficacy of Antiretroviral Therapy in Patients Infected with HIV B and non-B Subtypes strains in France, J. Acquir Immune Defic Syndr, Vol 56, N°2, February 1, 2011, 67-69
Access to aggregated data	Access on specific project only
Access to individual data	Access on specific project only