

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.
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Sign or acronym	BINOME
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CNIL registration number, number and date of CPP agreement, AFSSAPS (French Health Products Safety Agency) authorisation	CNIL n°906292
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General Aspects

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

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Organization	ABBVIE
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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 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