# 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

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| 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

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| Medical area | Infectious diseases |
| Health determinants | Occupation<br>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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| Name of the director | Cohen-Codar |
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| Organization | ABBVIE |



### Collaborations

| Funding | |
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| 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 |

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| | conditions for taking the treatment and the perception by the patient of the therapy and of its effects.<br>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:<br>- 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,<br>- any occurrence of clinical events,<br>- 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)<br>Adulthood (25 to 44 years)<br>Adulthood (45 to 64 years)<br>Elderly (65 to 79 years) |
| Population covered | Sick population |
| Gender | Male<br>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 |

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| **Data** | |
| Database activity | Data collection completed |
| Type of data collected | Clinical data<br>Declarative data<br>Biological data |
| Clinical data (detail) | Direct physical measures<br>Medical registration |
| Declarative data (detail) | Paper self-questionnaire<br>Face to face interview |
| Biological data (detail) | biological monitoring of the HIV infection |
| Presence of a biobank | No |
| Health parameters studied | Health event/morbidity<br>Health care consumption and services<br>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.<br><br>Distribution of the results of the study: (see the tab for more information)<br>Poster:<br>O. Bouchaud, V. Le Moing, F. Simon, P. NgoVan, P. |

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| | 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.<br>Article:<br>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 |