PREFACE - Study on the prevalence of facial lipoatrophy in patients infected by HIV virus receiving antiretroviral drugs - FRAN08-005

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General

Identification

Detailed name	Study on the prevalence of facial lipoatrophy in patients infected by HIV virus receiving antiretroviral drugs - FRAN08-005
Sign or acronym	PREFACE
CNIL registration number, number and date of CPP agreement, AFSSAPS (French Health Products Safety Agency) authorisation	908505

General Aspects

Medical area	Infectious diseases
Health determinants	Iatrogenic
Keywords	side-effects

Scientific investigator(s) (Contact)

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Organization	ABBVIE

Collaborations

Funding

Funding status	Private
Details	ABBOTT France et Sanofi Aventis

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.	Randomly selected doctors from a database of doctors working on HIV virus and identified in the file of the French medical board. Each doctor accepting to participate to the study will include his first 25 consecutive patients seen in consultation and responding to the eligibility criteria.
Database objective	
Main objective	Describe the prevalence of the facial lipoatrophy in patients infected by HIV virus and receiving antiretroviral drugs. Describe the prevalence of lipoatrophies and lipodystrophic mixed syndromes. Evaluate the score of quality of life, using the patients multi-dimensional auto-questionnaire and specific ABCD "Assessment of Body Change and Distress".
Inclusion criteria	Patient infected by HIV virus, receiving antiretroviral drugs for at least 1 month and coming to consultation at his usual follow-up center, during the period of the study, obtaining of the written consent for the collect and exploitation of his 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

Data collection

Dates	
Date of first collection (YYYY or MM/YYYY)	04/2009
Date of last collection (YYYY or MM/YYYY)	07/2009

Size of the database	
Size of the database (number of individuals)	[1000-10 000[individuals
Details of the number of individuals	2131

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
Biological data (detail)	Biological follow-up of the HIV infection.
Presence of a biobank	No
Health parameters studied	Health event/morbidity

	Health care consumption and services
Care consumption (detail)	Medicines consumption
Procedures	
Data collection method	Observation forms "patients" filled by the doctor and sent by mail to the society in charge of data management. Self-questionnaire ABCD filled by the patient and returned to the doctor in a sealed envelope, and then sent to the society in charge of data management.
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)	Raw data access procedure to be defined. Results diffusion through publications (posters and articles)
Access to aggregated data	Access on specific project only
Access to individual data	Access on specific project only