

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 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)
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Population covered	Sick population
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Gender	Male Woman
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Geography area	National
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Detail of the geography area	Metropolitan France
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Data collection

Dates

Date of first collection (YYYY or MM/YYYY)	04/2009
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Date of last collection (YYYY or MM/YYYY)	07/2009
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Size of the database

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

Database activity	Data collection completed
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Type of data collected	Clinical data Declarative data Biological data
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Clinical data (detail)	Direct physical measures Medical registration
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Declarative data (detail)	Paper self-questionnaire
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Biological data (detail)	Biological follow-up of the HIV infection.
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Presence of a biobank	No
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Health parameters studied	Health event/morbidity
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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