PROXAIR - Etude de PROXimologie dans l'Asthme persIstant sévèRe

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General

Identification

Detailed name	Etude de PROXimologie dans l'Asthme persIstant sévèRe
Sign or acronym	PROXAIR
CNIL registration number, number and date of CPP agreement, AFSSAPS (French Health Products Safety Agency) authorisation	--

General Aspects

Medical area	Pneumology
Others (details)	severe asthma
Keywords	asthma control quality of life spouse

Scientific investigator(s) (Contact)

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Unit	Direction Relations Économiques et Institutionnelles
Organization	Novartis Pharma

Collaborations

Funding

Funding status	Private
Details	Novartis Pharma S.A.S.

Governance of the database	
Sponsor(s) or organisation(s) responsible	Novartis Pharma S.A.S.
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 care professionals
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.	Each investigator propose to all his eligible patients to participate to the study. Patients fill in a questionnaire to assess the impact of his disease on his daily life, and is in chrage to hand over a specific questionnaires his spouse (if his spouse is not present at the consultation).
Database objective	
Main objective	Assess physical, psychic and socio-economic impact on patients and spouse of severe persistent asthma treated with high-dose inhaler steroids and long-acting ß2 agonists (LABA), according to the asthma control level
Inclusion criteria	Patient inclusion Criteria : - Ambulatory patients, able to cooperate, of either sex, at least 18 years of age. - Patients with severe persistent asthma receiving for at least three months a continuous and stable treatment of high-dose inhaler steroids (? 1 000 µg/d of beclometasone dipropionate excluding micronized forms in metered-dose inhalers, ? 800 µg/d of beclometasone dipropionate in micronized

	form in metered-dose inhalers or ? 800 µg/j of budesonide or ? 500 µg/d of fluticasone propionate) and of inhaled long-acting ß2 agonists, administered: either in the form of two specialties using one or two of the following inhalers: Aerolizer®, standard metered-dose inhaler, Autohaler?, Diskus®, Turbuhaler®, or in the form of a fixed association using one of the following inhalers: standard metered-dose inhaler, Diskus®, Turbuhaler®. - Patients with FEV measurement in the previous month. - Patients who brought their inhaled steroid treatment and inhaled long-acting ß2-agonist at the time of consultation. - Patients in couple whether or not married - Patients and relatives agree to participate Patient non-inclusion Criteria : - Patients with a non-asthmatic OCPD. - Patients who had inhaled steroids or lLABA treatment change in the previous three months (add-on or change of drug, posology change). - Patients and relatives refusing to participate to the study - Parents/ those close unable to complete a self-questionnaire. - Patients who do not live as a couple
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	General population
Gender	Male Woman
Geography area	National
Detail of the geography area	The study was carried out with a representative sample of pneumologist doctors with a hospital activity (exclusive or mixed) or with a solely liberal activity. The study was proposed by letter to all pneumologists exercising in France: 2089 pneumologists with hospital activity (exclusive or mixed) and 657 liberal pneumologists (Source: TVF, 4 January 2006).

Data collection

Dates

Date of first collection (YYYY or MM/YYYY)	2006
Date of last collection (YYYY or MM/YYYY)	2007

Size of the database

Size of the database (number of individuals)	< 500 individuals
Details of the number of individuals	280

Data

Database activity	Data collection completed
Type of data collected	Declarative data
Declarative data (detail)	Paper self-questionnaire
Presence of a biobank	No
Health parameters studied	Health event/morbidity Quality of life/health perception

Procedures

Data collection method	self-questionnaire filled in at home and returned by mail
Classifications used	GINA classification
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)	Methods for accessing the database are currently being defined

Access to aggregated data	Access on specific project only
Access to individual data	Access on specific project only