OCSIGEN - Follow-up cohort of asthmatic patient treated with inhaled corticosteroid

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General

Identification

Detailed name	Follow-up cohort of asthmatic patient treated with inhaled corticosteroid
Sign or acronym	OCSIGEN
CNIL registration number, number and date of CPP agreement, AFSSAPS (French Health Products Safety Agency) authorisation	CNIL

General Aspects

Medical area	Pneumology
Health determinants	Medicine
Keywords	inhaled steroids, cohort

Scientific investigator(s) (Contact)

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Unit	Laboratoire GSK

Collaborations

Funding

Funding status	Private
Details	GSK laboratory

Governance of the database

Sponsor(s) or organisation(s) responsible	Laboratoire GSK
Organisation status	Private

Additional contact

Main features

Type of database

Type of database	Study databases
Study databases (details)	Longitudinal study (except cohorts)
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.	GP section: The investigating physicians will be the Thalès physicians accepting to participate in the study Pneumologist section: The investigating centers for the study will be obtained by random drawing stratified over the region. The minimum survey rate allowing for representation of each of the regions is about 4%, which corresponds to a sample of 101 pneumologists in France

Database objective

Main objective	Describe the conditions of use of the fluticasone and other inhaled corticosteroids in a pragmatic situation in general practice and in specialized pneumology, evaluate the severity of the asthma of patients cared for and measure the adequacy of the care with the national recommendations
Inclusion criteria	GP section: The eligible population is defined by all of the asthmatic patients over the age of 15 years who have consulted at least twice in the previous year and in whom an inhaled corticotherapy is in progress (at least one prescription in the last six

	months). Patients defined as such who come to consult spontaneously for asthma during the period of inclusion will also be included. Refusal to participate and the association of the asthma with an OCPD are criteria for non-inclusion. Pneumologist section: Asthmatic persons cared for in liberal pneumology present in the practice of the investigators of the study and meeting the inclusion criteria
Population type	
Age	Adolescence (13 to 18 years) Adulthood (19 to 24 years) Adulthood (25 to 44 years) Adulthood (45 to 64 years) Elderly (65 to 79 years) Great age (80 years and more)
Population covered	Sick population
Gender	Male Woman
Geography area	National
Detail of the geography area	France
Data collection	
Dates	
Date of first collection (YYYY or MM/YYYY)	2004
Date of last collection (YYYY or MM/YYYY)	2009
Size of the database	
Size of the database (number of individuals)	[1000-10 000[individuals
Details of the number of individuals	1691
Data	
Database activity	Data collection completed
Type of data collected	Clinical data Declarative data

Clinical data (detail)	Direct physical measures Medical registration
Declarative data (detail)	Paper self-questionnaire
Presence of a biobank	No
Health parameters studied	Health care consumption and services
Care consumption (detail)	Hospitalization Medical/paramedical consultation Medicines consumption

Procedures

Data collection method	GP section:The characteristics of the patients will be collected in historical data present in the Thalès database, then at the inclusion visit and during all of the visits occurring during the follow-up period. At each visit, the stage of the severity of the patients according to GINA clinical and therapeutic classifications will be evaluatedDuring the inclusion period, at each consultation of an eligible patient, the study will be offered to him. Where applicable, the computerized inclusion questionnaire is filled out and the patient is included in the cohort. At each consultation carried out during the follow-up period, a ""pop-up"" screen containing the follow-up questionnaire will appear on the investigator's computer screen.Pneumologist section:The conditions for the use of inhaled steroids according to the stages of severity will be described through three questionnaires: a historical questionnaire (data coming from the medical dossier of the patient), an inclusion questionnaire and a follow-up questionnaire which will be implemented in computerized format. A fourth questionnaire, self-administered pertaining to the control of the asthma, will be completed by the patient at inclusion and at each visit during the follow-up. The collection of data will be carried out on a computerized support via a secure internet site devoted to the study. The physician will directly enter the information desired into the on-line forms
Participant monitoring	Yes
Details on monitoring of participants	GP section:Follow-up for 24 months, Pneumologist section:Follow-up for 24 months, at each new consultation carried out during the follow-up period, the pneumologist fills out the computerized on-line follow-up questionnaire

Links to administrative sources	No
Promotion and access	
Promotion	
Link to the document	http://tinyurl.com/pubmed-ocsigen
Description	Liste des publications dans Pubmed
Access	
Terms of data access (charter for data provision, format of data, availability delay)	Publications in progress
Access to aggregated data	Access on specific project only
Access to individual data	Access on specific project only