EXACO - Cohort of Patients with Chronic Obstructive Pulmonary Disease

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General

Identification

Detailed name	Cohort of Patients with Chronic Obstructive Pulmonary Disease
Sign or acronym	EXACO
CNIL registration number, number and date of CPP agreement, AFSSAPS (French Health Products Safety Agency) authorisation	CNIL

General Aspects

Medical area	Pneumology
Pathology (details)	Chronic obstructive pulmonary disease
Health determinants	Others (specify)
Keywords	bronchitis, COPD, exacerbation, cohort

Scientific investigator(s) (Contact)

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Collaborations

Funding

Funding status	Private
Details	AltanaPharma, Astra-Zeneca, Boehringer-Ingelheim, GlaxoSmithKline, Pfizer

Governance of the database

Sponsor(s) or organisation(s) responsible	Société de Pneumologie de Langue Française
Organisation status	Public

Additional contact

Main features

Type of database

Type of database	Study databases
Study databases (details)	Cohort study
Database recruitment is carried out by an intermediary	A selection of health care professionals
Additional information regarding sample selection.	One hundred and fifty investigating respiratory physicians forming a representative national sample of the profession, each including an average of 8 patients that meet the inclusion criteria.

Database objective

Main objective	The main aims of the study are to qualitatively and quantitatively describe the exacerbations in a cohort of COPD patients at different levels of severity and to confirm the existence of a sub-group of patients defined as frequent exacerbators who experience a high number of exacerbations over time. Where applicable, to determine the threshold value

	(number of exacerbations) that distinguishes frequent exacerbations by assuming that 3 exacerbations per year, regardless of severity, are sufficient to class the patient as a ?frequent? exacerbator. Several secondary aims will also be pursued. To identify factors associated with frequent exacerbators. To identify criteria more readily associated with exacerbation severity. To confirm the link between frequent exacerbators/accelerated decline in lung function. A validation of the VSRQ scale will be performed with the following metrics: replication; clinical validity through comparison with the St. George questionnaire; VSRQ unidimensional structure; VSRQ internal consistency; sensitivity to change; minimal important distance.
Inclusion criteria	Respiratory physicians (private practice or hospital: CHG, CHU) will enrol patients aged 40 and over with stage II or III COPD according to SPLF criteria (2003); smokers or ex-smokers (>15 pack-years); stable and with post-bronchodilator FEV1 lower than or equal to 80% of predicted value and FEV1/VC relationship <70%. Patients must accept and complete the self-monitoring log on a monthly basis and, at each exacerbation, can be contacted by phone every three months for 4 years. Participants shall sign a consent form. The following may not be included: patients with active tuberculosis, cancer (or who received cancer treatment in the last 3 years), diffuse bronchiectasis, cystic fibrosis, asthma (in clinical history), or any other diagnosed lung diseases (sarcoidosis, pulmonary fibrosis, pneumoconiosis, etc.). Other non-inclusion criteria include exacerbation one month prior to enrolment; absence of a telephone and participation in another clinical or epidemiological study.
Population type	
Age	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	France

Data collection

Dates

Date of first collection (YYYY or MM/YYYY)	2006
Date of last collection (YYYY or MM/YYYY)	2010

Size of the database

Size of the database (number of individuals)	[1000-10 000[individuals
Details of the number of individuals	835

Data

Database activity	Data collection completed
Type of data collected	Clinical data Declarative data
Clinical data (detail)	Direct physical measures Medical registration
Details of collected clinical data	Socio-demographic characteristics; clinical profile and ongoing treatment; breathlessness scales (MRC/Borg Score), Pulmonary Function testing (PFT); 6-minute walking test (TM6); impact on daily life; quality of life (VSRQ self-administered questionnaire). Optional tests are: blood oxygen saturation; sputum cytology examination (SCE); signs of emphysema on computed tomography (CT); measurement of blood gas levels. Body Mass Index; breathlessness measured with MRC scale and 6-minute walking test. During each follow-up visit; onset of exacerbation episodes as well as any changes occurring since the last visit will be made known.
Declarative data (detail)	Paper self-questionnaire Phone interview
Details of collected declarative data	Self-monitoring log (each occurrence of unusual respiratory distress for 2 days or more).

Presence of a biobank	No
Health parameters studied	Health event/morbidity Quality of life/health perception
Procedures	
Data collection method	Collected by hospital and/or private respiratory physicians.
Participant monitoring	Yes
Details on monitoring of participants	4-year follow-up following enrolment. Once a year, the results of a full pulmonary function test; 6-minute walking test and MRC breathlessness scale score will be gathered; the quality of life questionnaire and Borg Scale score will also be completed once a year. Tests will not be mandatory but carried out as part of the treatment course and regular follow-up of patients with COPD. The patient will complete the self-monitoring log when there is unusual respiratory distress for 2 days or more. He/she will also include his/her monthly respiratory progress in the log at the end of each follow-up month. A quarterly telephone interview where the telephone operator will ensure that all exacerbations were recorded in the log. Otherwise, data will be specified. This interview will minimise the risk of good response bias (the most suitable patients will better complete the questionnaire).
Links to administrative sources	No
Promotion and access	
Promotion	
Link to the document	http://www.em-consulte.com/rmr/article/134729
Access	
Terms of data access (charter for data provision, format of data, availability delay)	To be decided.
Access to aggregated data	Access on specific project only
Access to individual data	Access on specific project only