EXACO - Cohort of Patients with Chronic Obstructive Pulmonary Disease

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Général

Identification

Nom détaillé	Cohort of Patients with Chronic Obstructive Pulmonary Disease
Sigle ou acronyme	EXACO
Numéro d'enregistrement (ID-RCB ou EUDRACT, CNIL, CPP, etc.)	CNIL

Thématiques générales

Domaine médical	Pneumology
Pathologie, précisions	Chronic obstructive pulmonary disease
Déterminants de santé	Others (specify)
Mots-clés	bronchitis, COPD, exacerbation, cohort

Responsable(s) scientifique(s)

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Collaborations	
Financements	
Financements	Private
Précisions	AltanaPharma, Astra-Zeneca, Boehringer-Ingelheim, GlaxoSmithKline, Pfizer
Gouvernance de la base de données	
Organisation(s) responsable(s) ou promoteur	Société de Pneumologie de Langue Française
Statut de l'organisation	Secteur Public
Contact(s) supplémentaire(s)	
Caractéristiques	
Type de base de données	
Type de base de données	Study databases
Base de données issues d'enquêtes, précisions	Cohort study
Origine du recrutement des participants	A selection of health care professionals
Informations complémentaires concernant la constitution de l'échantillon	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.
Objectif de la base de données	
Objectif principal	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.
Critères d'inclusion	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.
Type de population	
Age	Adulthood (25 to 44 years) Adulthood (45 to 64 years) Elderly (65 to 79 years)
Population concernée	Sick population
Sexe	Male Woman

Champ géographique	National
Détail du champ géographique	France

Collecte

Dates

Année du premier recueil	2006
Année du dernier recueil	2010

Taille de la base de données

Taille de la base de données (en nombre d'individus)	[1000-10 000[individuals
Détail du nombre d'individus	835

Données

Activité de la base	Data collection completed
Type de données recueillies	Clinical data Declarative data
Données cliniques, précisions	Direct physical measures Medical registration
Détail des données cliniques recueillies	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.
Données déclaratives, précisions	Paper self-questionnaire Phone interview
Détail des données déclaratives recueillies	Self-monitoring log (each occurrence of unusual respiratory distress for 2 days or more).
Existence d'une biothèque	No

Paramètres de santé étudiés	Health event/morbidity Quality of life/health perception
Modalités	
Mode de recueil des données	Collected by hospital and/or private respiratory physicians.
Suivi des participants	Yes
Détail du suivi	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).
Appariement avec des sources administratives	No
Valorisation et accès	
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Lien vers le document	http://www.em-consulte.com/rmr/article/134729
Accès	
Charte d'accès aux données (convention de mise à disposition, format de données et délais de mise à disposition)	To be decided.
Accès aux données agrégées	Access on specific project only
Accès aux données individuelles	Access on specific project only