

PROXAIR - Etude de PROXimologie dans l'Asthme persIstant sévèRe

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Date de modification : 05/09/2017 | Version : 1 | ID : 175

Général	
Identification	
Nom détaillé	Etude de PROXimologie dans l'Asthme persIstant sévèRe
Sigle ou acronyme	PROXAIR
Numéro d'enregistrement (ID-RCB ou EUDRACT, CNIL, CPP, etc.)	--
Thématiques générales	
Domaine médical	Pneumology
Autres, précisions	severe asthma
Mots-clés	asthma control quality of life spouse
Responsable(s) scientifique(s)	
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Laboratoire	Direction Relations Économiques et Institutionnelles
Organisme	Novartis Pharma
Collaborations	
Financements	
Financements	Private
Précisions	Novartis Pharma S.A.S.
Gouvernance de la base de données	

Organisation(s) responsable(s) ou promoteur	Novartis Pharma S.A.S.
Statut de l'organisation	Secteur Privé
Contact(s) supplémentaire(s)	
Caractéristiques	
Type de base de données	
Type de base de données	Study databases
Base de données issues d'enquêtes, précisions	Not-repeated cross-sectional studies (except case control studies)
Origine du recrutement des participants	A selection of health care professionals
Critère de sélection des participants	Medication(s) taken
Le recrutement dans la base de données s'effectue dans le cadre d'une étude interventionnelle	No
Informations complémentaires concernant la constitution de l'échantillon	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 charge to hand over a specific questionnaire to his spouse (if his spouse is not present at the consultation).
Objectif de la base de données	
Objectif principal	Assess physical, psychic and socio-economic impact on patients and spouse of severe persistent asthma treated with high-dose inhaled steroids and long-acting β_2 agonists (LABA), according to the asthma control level
Critères d'inclusion	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 inhaled steroids ($\geq 1\,000\,\mu\text{g/d}$ of beclomethasone dipropionate excluding micronized forms in metered-dose inhalers, $\geq 800\,\mu\text{g/d}$ of beclomethasone dipropionate in micronized form in metered-dose inhalers or $\geq 800\,\mu\text{g/j}$ of

budesonide or ? 500 µg/d of fluticasone propionate) and of inhaled long-acting β 2 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 β 2-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 ILABA 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

Type de population

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 concernée	General population
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Sexe	Male Woman
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Champ géographique	National
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Détail du champ géographique	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).
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Collecte

Dates	
Année du premier recueil	2006
Année du dernier recueil	2007
Taille de la base de données	
Taille de la base de données (en nombre d'individus)	< 500 individuals
Détail du nombre d'individus	280
Données	
Activité de la base	Data collection completed
Type de données recueillies	Declarative data
Données déclaratives, précisions	Paper self-questionnaire
Existence d'une bibliothèque	No
Paramètres de santé étudiés	Health event/morbidity Quality of life/health perception
Modalités	
Mode de recueil des données	self-questionnaire filled in at home and returned by mail
Nomenclatures employées	GINA classification
Suivi des participants	No
Appariement avec des sources administratives	No
Valorisation et accès	
Valorisation et accès	
Accès	
Charte d'accès aux données (convention de mise à disposition, format de données et délais de mise à disposition)	Methods for accessing the database are currently being defined
Accès aux données agrégées	Access on specific project only

