

INHALER - Cross-sectional study on patients with chronic obstructive pulmonary disease: real-life evaluation of inhaler handling

Head :Molimard Mathieu, Université de Bordeaux - Department of Medical Pharmacology - CIC Bordeaux
CIC1401

Girodet Pierre-Olivier, Université de Bordeaux - Department of Medical Pharmacology - CIC Bordeaux
CIC1401

Last update : 10/27/2017 | Version : 1 | ID : 73245

General

Identification

Detailed name	Cross-sectional study on patients with chronic obstructive pulmonary disease: real-life evaluation of inhaler handling
---------------	--

Sign or acronym	INHALER
-----------------	---------

CNIL registration number, number and date of CPP agreement, AFSSAPS (French Health Products Safety Agency) authorisation	CCTIRS n° 14.615 - CNIL n° 914616
--	-----------------------------------

General Aspects

Medical area	Pneumology
--------------	------------

Pathology (details)	Chronic obstructive pulmonary disease
---------------------	---------------------------------------

Health determinants	Lifestyle and behavior Medicine
---------------------	------------------------------------

Keywords	Chronic obstructive pulmonary disease, inhaler handling, Department of Medical Pharmacology, Bordeaux Pharmacoépi, cross-sectional study
----------	--

Scientific investigator(s) (Contact)

Name of the director	Molimard
----------------------	----------

Surname	Mathieu
---------	---------

Address	146 rue Léo Saignat - Case 36 33076 BORDEAUX Cedex
---------	---

Phone	05 57 57 15 60
-------	----------------

Email	mathieu.molimard@u-bordeaux.fr
Unit	Université de Bordeaux - Department of Medical Pharmacology - CIC Bordeaux CIC1401
Organization	Université de Bordeaux
Name of the director	Girodet
Surname	Pierre-Olivier
Address	146 rue Léo Saignat - Case 36 33076 BORDEAUX
Phone	05 57 57 15 60
Email	pierre-olivier.girodet@u-bordeaux.fr
Unit	Université de Bordeaux - Department of Medical Pharmacology - CIC Bordeaux CIC1401
Organization	Université de Bordeaux
Collaborations	
Funding	
Funding status	Private
Details	Novartis Pharma S.A.S.
Governance of the database	
Sponsor(s) or organisation(s) responsible	Université de Bordeaux - Service de Pharmacologie médicale - CIC Bordeaux CIC1401
Organisation status	Public
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 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.	Patients were included prospectively between March and September 2015 by general practitioners and participating pneumologists.
Database objective	
Main objective	The main objective is to evaluate the real life handling of inhalers used by patients with obstructive pulmonary disease (COPD).
Inclusion criteria	<p>Diagnosis of COPD</p> <p>Age over 40 years</p> <p>Smoking over 10 packs per year</p> <p>Use by the patient, for at least 1 month, of a studied inhaler</p> <p>Exclusion criterion</p> <p>Pregnancy</p>
Population type	
Age	<p>Adulthood (25 to 44 years)</p> <p>Adulthood (45 to 64 years)</p> <p>Elderly (65 to 79 years)</p> <p>Great age (80 years and more)</p>
Population covered	Sick population
Pathology	X - Diseases of the respiratory system
Gender	<p>Male</p> <p>Woman</p>
Geography area	National
Detail of the geography area	Private-practice general practitioners and pneumologists in France
Data collection	
Dates	
Date of first collection (YYYY or MM/YYYY)	2015
Date of last collection (YYYY or MM/YYYY)	2015

Size of the database

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

Details of the number of individuals 5000

Data

Database activity Data collection completed

Type of data collected Clinical data
Declarative data

Clinical data (detail) Direct physical measures

Details of collected clinical data General characteristics of the patient (sex, age and comorbidities) - History of the COPD

Declarative data (detail) Face to face interview

Details of collected declarative data 1-Question the patient on his/her history of inhaler use 2- Question the patient on his/her perception of the inhalation carried out 3- Observation of the patient by the physician during the inhalation test

Presence of a biobank No

Health parameters studied Health care consumption and services
Quality of life/health perception

Care consumption (detail) Hospitalization
Medical/paramedical consultation
Medicines consumption

Quality of life/perceived health (detail) Perception of inhalation by the patient
(improvement of the respiratory condition)

Procedures

Data collection method Data from the study are collected through standardised paper questionnaires completed by participating physicians. The data are then entered into a specific study database.

Participant monitoring No

Followed pathology

Links to administrative sources No

Promotion and access

Promotion

Link to the document [ERJ-01794-2016 - corrected proof.pdf](#)

Access

Presence of document that lists variables and coding procedures Yes

Terms of data access (charter for data provision, format of data, availability delay) Ownership of and access to the study data were the subject of an agreement between the Université de Bordeaux and the laboratory. The terms of access to the database must be established by a request to the study's scientific advisory board.

Access to aggregated data Access on specific project only

Access to individual data Access on specific project only