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

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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)

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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 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	Diagnosis of COPD Age over 40 years Smoking over 10 packs per year Use by the patient, for at least 1 month, of a studied inhaler Exclusion criterion Pregnancy

Population type

Age	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
Pathology	X - Diseases of the respiratory system
Gender	Male Woman
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