THEATRE - Observational study of the therapeutic strategy for management of acute exacerbation of chronic bronchitis in real-life practice

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General

Identification

Detailed name	Observational study of the therapeutic strategy for management of acute exacerbation of chronic bronchitis in real-life practice
Sign or acronym	THEATRE
CNIL registration number, number and date of CPP agreement, AFSSAPS (French Health Products Safety Agency) authorisation	CCTI-RS 06.139, CNIL 906126

General Aspects

Medical area	Pneumology
Health determinants	Medicine
Others (details)	Chronic Obstructive Pulmonary Disease (COPD), acute exacerbation of chronic bronchitis (AECB)
Keywords	effectiveness, therapeutic strategies, pharmacoepidemiology, cohort, Department of Pharmacology, Bordeaux

Scientific investigator(s) (Contact)

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Collaborations

Funding

Funding status	Private
Details	Laboratoire Sanofi-Aventis (soutien inconditionnel) - Sanofi-Aventis (unconditional support)

Governance of the database

Sponsor(s) or organisation(s) responsible	INSERM
Organisation status	Public

Additional contact

Main features

Type of database

Type of database	Study databases
Study databases (details)	Longitudinal study (except cohorts)
Database recruitment is carried out by an intermediary	A selection of health care professionals An administrative base or a register
Database recruitment is carried out as part of an interventional	No

study	
Additional information regarding sample selection.	A database of general practitioners and non-hospital pneumologists provided by Cegedim was used for selection of physicians. General practitioners and non-hospital pneumologists were to include 5000 patients with an AECB episode. The physicians were also asked to identify and register all patients with AECB episode diagnosed according to their own criteria (with a maximum of 20 patients).
Database objective	
Main objective	The study objectives were to describe how the management of AECB in real-life conditions of prescription and to assess the effectiveness of the therapeutic strategies used.
Inclusion criteria	The study objectives were to describe how the management of AECB in real-life conditions of prescription and to assess the effectiveness of the therapeutic strategies used.
Population type	
Age	Adulthood (19 to 24 years) 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
Gender	Male Woman
Geography area	National
Detail of the geography area	General practitioners and non-hospital pneumologists in metropolitan France
Data collection	
Dates	
Date of first collection (YYYY or MM/YYYY)	2006
Date of last collection (YYYY or MM/YYYY)	2007
Size of the database	

Size of the database (number of individuals)	[1000-10 000[individuals
Details of the number of individuals	4994
Data	
Database activity	Data collection completed
Type of data collected	Clinical data
Clinical data (detail)	Direct physical measures
Presence of a biobank	No
Health parameters studied	Health event/morbidity Health event/mortality Health care consumption and services
Care consumption (detail)	Hospitalization Medical/paramedical consultation Medicines consumption
Procedures	
Data collection method	Patients included were the subject of collection of indirectly personal medical data (medical questionnaire completed by the physician).
Participant monitoring	Yes
Details on monitoring of participants	Patients were followed by physicians until 30 April 2007, the end of the winter period (four to seven months of follow-up according to the inclusion date), with an interim evaluation point in case of first new consultation for AEBC and for all patients at end of study.
Links to administrative sources	No
Promotion and access	
Promotion	
Access	
Terms of data access (charter for data provision, format of data, availability delay)	Patients were followed by physicians until 30 April 2007, the end of the winter period (four to seven months of follow-up according to the inclusion date), with an interim evaluation point in case of

	first new consultation for AEBC and for all patients at end of study.
Access to aggregated data	Access on specific project only
Access to individual data	Access on specific project only