

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
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Details of the number of individuals	4994
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Data

Database activity	Data collection completed
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Type of data collected	Clinical data
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Clinical data (detail)	Direct physical measures
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Presence of a biobank	No
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Health parameters studied	Health event/morbidity Health event/mortality Health care consumption and services
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Care consumption (detail)	Hospitalization Medical/paramedical consultation Medicines consumption
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Procedures

Data collection method	Patients included were the subject of collection of indirectly personal medical data (medical questionnaire completed by the physician).
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Participant monitoring	Yes
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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.
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Links to administrative sources	No
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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
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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