# 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

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|---|---|
| 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

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|---|---|
| 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

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

## Governance of the database

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

## Additional contact

## Main features

## Type of database

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| 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<br>An administrative base or a register |
| Database recruitment is carried out as part of an interventional | No |

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| 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)<br>Adulthood (25 to 44 years)<br>Adulthood (45 to 64 years)<br>Elderly (65 to 79 years)<br>Great age (80 years and more) |
| Population covered | Sick population |
| Gender | Male<br>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** | |

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| 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<br>Health event/mortality<br>Health care consumption and services |
| Care consumption (detail) | Hospitalization<br>Medical/paramedical consultation<br>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 |

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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 |