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A non-interventional study analyzing the characteristics of patients hospitalized in France for acute exacerbations of COPD and the factors predicting disease progression

Submission date
05/09/2025

Recruitment status
Recruiting

Registration date
10/09/2025

Overall study status
Ongoing

Last Edited
08/09/2025

Condition category
Respiratory

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Chronic obstructive pulmonary disease (COPD) is a public health problem with more than 3 million patients in France. The rate of exacerbations in COPD patients varies from patient to patient and over time. The best predictor of exacerbations is a history of exacerbations (two or more exacerbations per year). Worsening respiratory function is associated with an increased prevalence of exacerbations. This study aims to describe the characteristics of COPD patients admitted to hospital for acute exacerbation in 2025 and to study death rates at 3 months and 3 years and risk factors and compare these data with those of the EA-BPCO study conducted in 2006.

Who can participate?
Patients aged 18 years and over who were hospitalized for an acute exacerbation linked to COPD (whether known or not) between 01/11/2025 and 31/11/2026

What does the study involve?
Data collection:
1. At inclusion: patient demographics, COPD history, comorbidities, medications, vaccinations, and clinical data at exacerbation onset
2. During hospitalization: patient pathway, treatments, ICU stay if applicable
3. Follow-up: 3–9 months – reassessment of COPD and ongoing treatments; 3 years – vital status and cause of death

What are the possible benefits and risks of participating?
None

Where is the study run from?
Centre Hospitalier Eure-Seine – Hôpital d'Evreux-Vernon (France)

When is the study starting and how long is it expected to run for?
November 2025 to September 2029

Who is funding the study?
1. Chiesi
2. AstraZeneca
3. Sanofi
4. SOS Oxygen
5. ASTEN
6. ASDIA
7. Homeperf

Who is the main contact?
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Additional identifiers

Clinical Trials Information System (CTIS)
2024-A02419-38

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
EA-COPD-CPHG Study: Predictive factors of 3-year survival in patients hospitalized for acute exacerbations of COPD in the pulmonology departments of general hospitals, from November 1, 2025, to October 31, 2026

Acronym
EA-COPD-CPHG

Study objectives
In 2024, COPD affects between 1.6 and 3 million patients in France. Over the past 15 years, its landscape has changed significantly. With an aging population, patients present with increasingly complex profiles and more frequent comorbidities. At the same time, healthcare organization has evolved: reduction in the number of full hospital beds, expansion of partial hospitalization, and increased availability of home-based care.

COPD management has also progressed. Recognition of the inflammatory component of the disease has led to wider use of inhaled triple therapy (LABA–LAMA–ICS) and the development of biologics (anti-IL-4/IL-13, anti-IL-5, anti-IL-33). Beyond pharmacological strategies, home oxygen therapy, pulmonary rehabilitation, and patient education have also reshaped COPD care in recent years.

In this context, establishing a new prospective observational real-world study, mirroring the EA-COPD study conducted in 2006, is highly relevant. It will allow us to:
1. Describe, in 2025, the characteristics of COPD patients hospitalized for acute exacerbations (AEs)
2. Identify potential subtypes (“phenotypes” or “endotypes”) of exacerbations

3. Assess 3-month and 3-year survival and associated risk factors
4. Compare these data with those from the 2006 study

Primary Objective:
To assess 3-year survival and predictive factors of survival in patients hospitalized for acute exacerbations (AEs) of chronic obstructive pulmonary disease (COPD).

Secondary Objectives:
1. To evaluate predictive factors of 3-month survival in patients hospitalized for AE of COPD.
2. To explore the existence of subtypes ("phenotypes/endotypes") of exacerbations.
3. To describe patient characteristics, COPD features, and management prior to hospitalization in patients with COPD admitted for AE.
4. To describe in-hospital management of COPD exacerbations (therapeutics, patient characteristics, follow-up, etc).
5. To compare the evolution of patient characteristics, COPD features, and management since 2006.
6. To assess the seasonality of COPD exacerbations.
7. To evaluate the impact of social deprivation on 3-year survival in patients hospitalized for AE of COPD

Ethics approval required
Ethics approval not required

Ethics approval(s)

Study design
Prospective observational national multicenter non-interventional cohort study

Primary study design
Observational

Study type(s)
Diagnostic, Prevention, Treatment

Health condition(s) or problem(s) studied
Chronic obstructive pulmonary disease (COPD)

Interventions
Data collection:
1. At inclusion: patient demographics, COPD history, comorbidities, medications, vaccinations, and clinical data at AE onset
2. During hospitalization: patient pathway, treatments, ICU stay if applicable
3. Follow-up: 3–9 months – reassessment of COPD and ongoing treatments; 3 years – vital status and cause of death

Analysis:
Data will be analyzed using R software. Descriptive statistics, comparisons between groups, and methods to identify AE subtypes will be applied. Survival will be assessed using Kaplan-Meier and Cox regression, including socio-economic factors for analysis of social deprivation effects. Time-series analyses will evaluate seasonality.

Intervention Type
Other

Primary outcome(s)
3-year survival of patients hospitalized for acute exacerbations (AE) of COPD, along with the predictive factors associated with this survival, measured using the patient's vital status at 3 years

Key secondary outcome(s))
1. 3-month survival of patients hospitalized for acute exacerbations (AE) of COPD, along with the predictive factors associated with this survival, measured using the patient's vital status at 1 year
2. Existence of subtypes of exacerbations, defined by the presence of (at the time of patient inclusion):
2.1. Comorbidities (asthma, history of Pseudomonas aeruginosa infection, presence of alpha-1 antitrypsin deficiency, respiratory allergies, bronchiectasis, emphysema, gastroesophageal reflux, stroke, dyslipidemia, ischemic heart disease, peripheral artery disease (PAD), heart failure, cardiac arrhythmias, hypertension (high blood pressure), osteoporosis, diabetes, lung cancer)
2.2. Biological values
3. The characteristics of patients, COPD, and its management prior to hospitalization in patients with COPD admitted to hospital for exacerbations, defined by:
3.1. Patient characteristics: sex, age, height, weight, smoking status
3.2. Management prior to hospitalization: previously diagnosed COPD, medically followed for COPD, prior treatments
4. The hospitalization management of COPD exacerbations, assessed during the patient's hospital stay for the exacerbation (that led to inclusion), using the following criteria: mode of admission to the department, management of the exacerbation in critical care, treatments administered during hospitalization, discharge procedures, and treatments prescribed at discharge.
5. The evolution of patient characteristics, COPD, and its management since 2006, assessed by comparing the data collected at inclusion in the 2006 EA-BPCO study with those collected at inclusion in the 2025/2026 study.
6. The seasonality of COPD exacerbations, assessed based on the number of patients included in the study across the four seasons of the year
7. The impact of social deprivation on 3-year survival of patients admitted to hospital for acute exacerbations, assessed by combining the social deprivation score at inclusion with the patients' vital status at 3 years

Completion date
30/09/2029

Eligibility

Key inclusion criteria
1. Age ≥18 years
2. All patients hospitalized in a pulmonology department for an acute exacerbation (AE) of COPD, whether previously diagnosed or newly identified, admitted between 01/11/2025 and 31/10/2026, regardless of:
2.1. Mode of admission (emergency, outpatient consultation, direct admission, intensive care

unit, other department), or
2.2. Associated conditions (e.g., obstructive sleep apnoea/hypopnoea syndrome [OSAHS], obesity-hypoventilation syndrome, etc)

Also eligible:
1. Patients with decompensation initially admitted to pulmonology and subsequently transferred to intensive care
2. Patients already receiving ventilatory support (long-term oxygen therapy, non-invasive ventilation)
3. Patients for whom COPD is diagnosed as a result of the index AE

Patient information sheet provided and explained; oral consent or absence of objection obtained.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
100 years

Sex
All

Key exclusion criteria
1. Age <18 years
2. Previous inclusion in the study
3. Patients unable to perform pulmonary function tests, cooperate with the protocol, or respond to questions
4. Patients deprived of liberty following a judicial or administrative decision
5. Patients unable to give consent

Date of first enrolment
01/11/2025

Date of final enrolment
30/09/2026

Locations

Countries of recruitment
France

Study participating centre
Centre Hospitalier Eure-Seine – Hôpital d'Evreux-Vernon
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Sponsor information

Organisation
Collège des Pneumologues des Hôpitaux Généraux (CPHG)

Funder(s)

Funder type
Industry

Funder Name
Chiesi Farmaceutici

Alternative Name(s)
Chiesi Pharmaceuticals, CHIESI Farmaceutici S.p.A., CHIESI, CHIESI GROUP

Funding Body Type
Private sector organisation

Funding Body Subtype
For-profit companies (industry)

Location
Italy

Funder Name
AstraZeneca

Alternative Name(s)
AstraZeneca PLC, Pearl Therapeutics, AZ

Funding Body Type
Government organisation

Funding Body Subtype
For-profit companies (industry)

Location
United Kingdom

Funder Name
Sanofi

Alternative Name(s)
sanofi-aventis, Sanofi US, Sanofi-Aventis U.S. LLC, Sanofi U.S.

Funding Body Type
Government organisation

Funding Body Subtype
For-profit companies (industry)

Location
United States of America

Funder Name
SOS Oxygen

Funder Name
ASTEN

Funder Name
ASDIA

Funder Name
Homeperf

Results and Publications

Individual participant data (IPD) sharing plan
In accordance with French data protection laws, individual participant data from the study cannot be disclosed outside the approved legal and protocol framework. Only aggregated or

anonymized data can be shared for research purposes, ensuring the confidentiality and protection of study participants.

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Protocol file			08/09/2025	No	No