

# WEUSKOP6416: Evaluating severe events in patients with Chronic Obstructive Pulmonary Disease (COPD) to inform risk minimization: A Retrospective Observational Study (116952)

**First published:** 13/06/2013

**Last updated:** 23/04/2024

Study

Finalised

## Administrative details

### EU PAS number

EUPAS4093

### Study ID

42072

### DARWIN EU® study

No

### Study countries

☐ United Kingdom

## Study description

The overall objectives COPD cohort study were to estimate the association between risk factors and pneumonia, including ICS-containing medications and to evaluate differences in clinical characteristics between patients who do and do not develop pneumonia. This is a retrospective observational study in the UK used linked primary and secondary care data with vital statistics. Patients were required to be new users of inhaled-corticosteroid-containing medications or long-acting bronchodilators from 2002-2010. Patients were  $\geq 45$  years of age, with  $\geq 1$  year of data prior to cohort entry for assessment of patient characteristics. Pneumonia events were compared using Cox models using propensity scores to control for confounding. New users were censored at earliest of: pneumonia event, death, switching/stopping treatment, or end of study period. Sensitivity of the results to different pneumonia definitions was evaluated in addition to varying the lag time before pneumonia events.

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## Study status

Finalised

## Contact details

### Study institution contact

GSK Clinical Disclosure Advisor GSK Clinical Disclosure  
Advisor [cdr\\_mailbox@gsk.com](mailto:cdr_mailbox@gsk.com)

**Study contact**

[cdr\\_mailbox@gsk.com](mailto:cdr_mailbox@gsk.com)

### Primary lead investigator

Darnella Streeter-Edwards Regulated Clinical Support  
Consultant

## Study timelines

### **Date when funding contract was signed**

Actual: 24/07/2012

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### **Study start date**

Actual: 24/07/2012

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### **Data analysis start date**

Actual: 24/07/2012

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### **Date of final study report**

Actual: 02/05/2013

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

GlaxoSmithKline- R&D

## Study protocol

[Redacted Prot-Amend1-F1-WEUSKOP6416-P \(2\).pdf](#)(412.67 KB)

## Regulatory

**Was the study required by a regulatory body?**

No

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**Is the study required by a Risk Management Plan (RMP)?**

Not applicable

## Methodological aspects

Study type

Study type list

**Study topic:**

Disease /health condition

Human medicinal product

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**Study type:**

Non-interventional study

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**Scope of the study:**

Assessment of risk minimisation measure implementation or effectiveness

**Data collection methods:**

Secondary use of data

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**Main study objective:**

Any severe pneumonia. Pneumonia that resulted in pneumonia hospitalization or overall mortality during the pneumonia episode. As a sensitivity analysis,

hospitalized pneumonia was examined further, as primary cause on any episode within a spell (hospitalization) and as a primary cause on the first episode within a spell.

## Study Design

### **Non-interventional study design**

Cohort

## Study drug and medical condition

### **Anatomical Therapeutic Chemical (ATC) code**

(R03AC) Selective beta-2-adrenoreceptor agonists

Selective beta-2-adrenoreceptor agonists

(R03BA) Glucocorticoids

Glucocorticoids

(R03BB) Anticholinergics

Anticholinergics

(R03CK) Adrenergics and other drugs for obstructive airway diseases

Adrenergics and other drugs for obstructive airway diseases

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### **Medical condition to be studied**

Chronic obstructive pulmonary disease

## Population studied

## **Short description of the study population**

Chronic Obstructive Pulmonary Disease (COPD) patients.

### **Inclusion Criteria**

Patients are required to:

1. Have CPRD-GOLD data of acceptable research quality according to CPRD standards.
2. Be new users of LABD or ICS-containing medications from January 2002-December 2010
3. Have a COPD diagnosis at any time in the period prior to and including the Cohort Entry Date (to eliminate any patients with asthma only)
4. Have at least one year of data prior to Cohort Entry Date.
5. Be at least 45 years of age at Cohort Entry Date.
6. Have GPRD-HES linkage. (Note: these individuals need to be retained for basic demographics but are not part of the new user cohort).
7. Have HES coverage one year prior to the Cohort Entry Date

### **Exclusion Criteria**

1. Patients with an occurrence of a code for a medical condition incompatible with COPD diagnosis any time in their history. This list contains conditions that are a related to lung or bronchial developmental anomalies, degenerative processes (cystic fibrosis, pulmonary fibrosis), bronchiectasis, pulmonary resection or other significant respiratory disorders other than COPD (but not including cancer) that can interfere with clinical COPD diagnosis or substantially change the natural history of the disease.
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## **Age groups**

Adults (46 to < 65 years)

Adults (65 to < 75 years)

Adults (75 to < 85 years)

Adults (85 years and over)

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### **Special population of interest**

Other

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### **Special population of interest, other**

Chronic Obstructive Pulmonary Disease (COPD) patients

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### **Estimated number of subjects**

18000

## Study design details

### **Outcomes**

The primary outcome was severe pneumonia. The secondary outcome was all pneumonias combined, including those that were considered severe and those that were not considered severe.

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### **Data analysis plan**

This was a retrospective observational study in the United Kingdom using linked primary and secondary care data with vital statistics. Pneumonia and pneumonia hospitalization events in subjects with COPD were compared in new users defined as an initial prescription of ICS-containing medications (n=11,555, ICS, ICS/LABA combination) and inhaled LABD monotherapies (n=6,492, LABA, LAMA) using Cox models (hazard ratios HR and 95% confidence intervals CI) and propensity scores with inverse proportional treatment weighting (IPTW) to control for confounding. New users were censored at earliest of: pneumonia event, death, switching/stopping treatment, or end of study period. Sensitive and specific pneumonia outcomes were examined including any pneumonia and severe pneumonia resulting in hospitalization or death during the episode.

Hospitalized pneumonia was examined further, as primary cause on any episode within a spell and as a primary cause on the first episode within a spell.

## Documents

### Study results

[116952-clinical-study-report-redact.pdf](#)(1.1 MB)

[CTR\\_WEUSKOP6416\\_116952\\_CSR\\_posting\\_6May2013\\_DH.pdf](#)(179.47 KB)

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## Data management

### ENCEPP Seal

The use of the ENCePP Seal has been discontinued since February 2025. The ENCePP Seal fields are retained in the display mode for transparency but are no longer maintained.

## Data sources

### Data source(s)

Clinical Practice Research Datalink

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### Data source(s), other

CPRD, Hospital Episode Statistics (HES)

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## **Data sources (types)**

Electronic healthcare records (EHR)

Other

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## **Data sources (types), other**

Prospective patient-based data collection

# Use of a Common Data Model (CDM)

## **CDM mapping**

No

# Data quality specifications

## **Check conformance**

Unknown

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## **Check completeness**

Unknown

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## **Check stability**

Unknown

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## **Check logical consistency**

Unknown

# Data characterisation

**Data characterisation conducted**

No