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

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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 ≥ 45 years of age, with ≥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.

Study status

Finalised

Contact details

Study institution contact

GSK Clinical Disclosure Advisor GSK Clinical Disclosure Advisor cdr_mailbox@gsk.com

Study contact

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Primary lead investigator

Darnella Streeter-Edwards Regulated Clinical Support Consultant

Primary lead investigator

Study timelines

Date when funding contract was signed
Actual: 24/07/2012

Study start date
Actual: 24/07/2012

Data analysis start date
Actual: 24/07/2012

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

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

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Data collection methods:

Secondary use of data

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

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.

Age groups

- Adults (46 to < 65 years)
- Adults (65 to < 75 years)
- Adults (75 to < 85 years)
- Adults (85 years and over)

Special population of interest

Other

Special population of interest, other

Chronic Obstructive Pulmonary Disease (COPD) patients

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.

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)

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

Data source(s), other

CPRD, Hospital Episode Statistics (HES)

Data sources (types)

Electronic healthcare records (EHR)

Other

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

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

No