

# Implications of ICS withdrawal in the real-life management of COPD

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Study

Finalised

## Administrative details

### EU PAS number

EUPAS30851

### Study ID

41925

### DARWIN EU® study

No

### Study countries

United Kingdom

### Study description

This will be a retrospective study using electronic medical records and linked COPD questionnaire data from the Optimum Patient Care Research Database (OPCRD). The study will evaluate the effect of ICS cessation in patients with

confirmed COPD, managed in a primary care, “real-life” setting. Specifically, it will compare the exacerbation rates and lung function of patients who stop ICS therapy to those who continue on triple therapy.

## Study status

Finalised

## Research institutions and networks

### Networks

#### Respiratory Effectiveness Group (REG)

- Belgium
- Denmark
- France
- Germany
- Greece
- Hungary
- Italy
- Netherlands
- Spain
- Sweden
- United Kingdom

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**Network**

**ENCePP partner**

# Contact details

## **Study institution contact**

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**Study contact**

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## **Primary lead investigator**

Helgo Magnussen

**Primary lead investigator**

# Study timelines

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

Planned: 30/08/2019

Actual: 03/09/2019

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## **Study start date**

Planned: 02/09/2019

Actual: 10/09/2019

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## **Data analysis start date**

Planned: 01/10/2019

Actual: 02/12/2019

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## **Date of final study report**

Planned: 13/01/2020

Actual: 26/10/2020

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# Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Boehringer Ingelheim

## 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

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##### **Study type:**

Non-interventional study

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##### **Scope of the study:**

Effectiveness study (incl. comparative)

**Data collection methods:**

Secondary use of data

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**Main study objective:**

Evaluate the effect of ICS cessation in patients with confirmed COPD, managed in a primary care, “real-life” setting. Specifically investigating the effects of ICS withdrawal on - 1) Exacerbation rates 2) Lung function

## Study Design

**Non-interventional study design**

Cohort

Other

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**Non-interventional study design, other**

Observational comparative effectiveness study

## Study drug and medical condition

**Medical condition to be studied**

Chronic obstructive pulmonary disease

## Population studied

**Short description of the study population**

Chronic obstructive pulmonary disease patients.

Patients were required to have  $\geq 2$  fixed dose ICS/LABA and separate LAMA

prescriptions, or  $\geq 2$  fixed dose ICS/LABA/LAMA prescriptions, in the baseline year. The IPD for the cessation group was the first prescription for a single LABA alongside a single LAMA, or a fixed dose LABA/LAMA, without ICS.

The control group patients were required to have  $\geq 1$  fixed or free combination of ICS/LABA/LAMA in the outcome year. Their index prescription date (IPD) was the date when the patient received a repeated prescription for their baseline triple therapy.

Patients were required to have an IPD prior to 1/12/2018 to allow for a 1-year outcome period; in patients with more than one IPD the first IPD was used for analysis.

Inclusion criteria were: (A) spirometry-confirmed diagnosis of COPD (Read code and FEV1/FVC  $< 0.7$  within 2 years, ever recorded); (B) aged  $\geq 40$  years at IPD; (C) current or ex-smoker; (D) have  $\geq 1$  year of continuous patient records in prior to IPD; and (E) ICS medication possession ratio (MPR, (Number of days supplied in period/Days in period)  $\times 100$ )  $\geq 70\%$  in the baseline year.

Exclusion criteria were: (A) asthma Read code during the baseline year; (B) prescribed azithromycin or roflumilast or receiving maintenance treatment with systemic steroids. Patients were excluded from the control group if they had ever had an ICS cessation prior to IPD.

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## **Age groups**

- Adults (18 to  $< 46$  years)
- 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**

3000

# Study design details

## **Outcomes**

Time to COPD exacerbation, Exacerbation rate/ Change in FEV1/ Time to addition or change in therapy/ ICS containing treatment adherence/ CAT score/ MRC Dyspnea scale/ Time to last record in database where there is a lack of continuous records (proxy for mortality)/ Time to first consultation with a pneumonia Read code

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## **Data analysis plan**

Assuming that the rate of drop out from the database/mortality rate (where recorded) are not significantly different between the ICS cessation and control arm then only those patients with  $\geq 1$  year of continuous database records post IPD date will be included in the multivariate regression analyses. We will use an intention to treat analysis. Multivariate regression analyses will be used to adjust for confounding variables. Primary outcome - time to event will be analysed using conditional cox proportional hazards regression. Secondary outcomes- will be analysed with conditional logistic, poisson or cox regression, as appropriate.

# Documents

## **Study publications**

Magnussen H, Lucas S, Lapperre T, Quint JK, Dandurand RJ, Roche N, Papi A, Pric...

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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)**

Optimum Patient Care Research Database

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### **Data source(s), other**

Optimum Patient Care Research Database (OPCRD)

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### **Data sources (types)**

[Electronic healthcare records \(EHR\)](#)

## 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