

# Metabolic effects associated with ICS (inhaled corticosteroid) use in COPD (chronic obstructive pulmonary disease) patients with type II diabetes

**First published:** 20/06/2014

**Last updated:** 15/05/2015

Study

Finalised

## Administrative details

### EU PAS number

EUPAS6804

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### Study ID

9743

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### DARWIN EU® study

No

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### Study countries

 United Kingdom

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### Study description

Lay Summary: Current international guidelines for the management of chronic obstructive pulmonary disease (COPD, GOLD 2014) recommend inhaled corticosteroids (ICS) are reserved for COPD patients with severe/very severe disease and/or frequent exacerbations. However, research shows widespread use of ICS in patients with mild and moderate disease, meaning more patients are exposed to risks of side effects than would be expected under current guidelines. High doses of ICS as those typically prescribed to COPD patients have been linked to increased risks of diabetes onset and progression, yet no study has investigated this association in a cohort of COPD patients in the UK. The proposed study will investigate whether ICS treatment in COPD patients with comorbid type II diabetes has a negative impact on diabetic control, and determine whether COPD patients treated with ICS outside of guidelines are at unnecessary risk of diabetes progression. The intended audience for this study is prescribers. We plan to publish the results of this study initially at a conference, then as a manuscript in a peer-reviewed journal.

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### **Study status**

Finalised

## Research institutions and networks

### Institutions

#### Research in Real Life

**First published:** 01/02/2024

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**Institution**

## Contact details

### Study institution contact

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Study contact

david@rirl.org

### Primary lead investigator

Rafael Mares

Primary lead investigator

## Study timelines

### Date when funding contract was signed

Actual: 04/06/2014

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### Study start date

Planned: 01/07/2014

Actual: 01/08/2014

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### Data analysis start date

Planned: 21/07/2014

Actual: 11/08/2014

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### Date of interim report, if expected

Planned: 31/08/2014

Actual: 07/11/2014

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### Date of final study report

Planned: 15/04/2015

Actual: 15/04/2015

## Sources of funding

- Pharmaceutical company and other private sector
- Other

## More details on funding

Boehringer Ingelheim, RiRL

## Study protocol

[ENCePP protocol submission - ICS-diabetes-COPD.pdf](#) (316.08 KB)

## Regulatory

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

No

## Methodological aspects

Study type

Study type list

**Study topic:**

Human medicinal product

Disease /health condition

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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:**

To assess whether ICS use (within and outside of GOLD guidelines) is associated with an increase in glycated haemoglobin (HbA1c) value (%) in COPD patients with type II diabetes.

## Study Design

**Non-interventional study design**

Cohort

## Study drug and medical condition

**Anatomical Therapeutic Chemical (ATC) code**

(R03B) OTHER DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, INHALANTS

OTHER DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, INHALANTS

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## **Medical condition to be studied**

Type 2 diabetes mellitus

Chronic obstructive pulmonary disease

## Population studied

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

COPD patients with comorbid type II diabetes aged  $\geq 40$  years at index date.

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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 with comorbid diabetes mellitus

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### **Estimated number of subjects**

1088

## Study design details

## Outcomes

Change in HbA1c value (%) relative to baseline. (a) Change in HbA1c with a change in anti-diabetic medication - (b) Change in number of patients on/off HbA1c target (< 7.5% as per UK QOF indicators) with no change in anti-diabetic medication - (c) No change in HbA1c with an increase in GP visits, hospital visits and glucose strip use - (d) Progression of ongoing diabetes treatment to insulin

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## Data analysis plan

This will be a retrospective cohort study with a one year outcome period after an index prescription date. The index prescription date refers to either the first prescription of ICS (ICS-initiating cohort) or the first prescription of LABA or LAMA (no ICS therapy cohort). Patients in the ICS-initiating cohort will be matched to patients in the no ICS therapy cohort (i.e. control cohort), using a set of baseline characteristics. For the primary outcome, mean one-year change in HbA1c value (%) will be compared across the two study cohorts. Internal validity will be addressed by matching patients on baseline characteristics and controlling for potential confounders during statistical analyses. External validity will be achieved by using large primary care databases, which have been shown to be generalizable to the UK population.

## 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**

Optimum Patient Care Research Database (OPCRD) United Kingdom

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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