# Burden and consequences of the use of COPD-related systemic corticosteroids (OCS COPD study)

**First published:** 24/06/2020

**Last updated:** 21/02/2024

Study Planned

## Administrative details

**PURI**

https://redirect.ema.europa.eu/resource/47531

**EU PAS number**

EUPAS35975

**Study ID**

47531

**DARWIN EU® study**

No

**Study countries**

☐ United Kingdom

**Study description**

This will be an observational, retrospective cohort study of patients who are or were diagnosed with COPD. Patterns of use, risk of comorbidities associated with COPD-related systemic corticosteroids use, and related cost impact on COPD patients in the CPRD database will be evaluated. Those initiating SCS (SCS arm) will be compared to those not exposed to SCS (non-SCS arm/control arm). This cohort study will be comprised of a minimum 1-year baseline period. The index date for patients in the SCS arm is the date of their first recorded prescription for parenteral or oral COPD-related corticosteroids while the index date for those in the non-SCS arm is the nearest general practice (GP) visit to the matched-case index date. Patients will be followed-up to the end of their individual records which will be defined as either of the following: date of the last data extraction from the GP, date of leaving the GP, date of death, or any study outcome of interest.The study outcome of interest is the incidence of comorbidity outcomes: type 2 diabetes mellitus, hypertension, cardio-/cerebrovascular disease (myocardial infarction, dyslipidaemia, congestive heart failure, cerebrovascular accident), osteoporosis, osteoporotic fracture, weight gain, sleep disorders, sleep apnoea, peptic ulcer, cataracts, glaucoma, depression/anxiety, psychosis, pneumonia, antibiotic treated infections, sudden death, and renal impairment. The worsening or recurrence of morbidity outcomes: type 2 diabetes, new osteoporosis related fractures, and pneumonia. HCRU and associated costs to the healthcare system will be described for different resource components as well as SCS-related all-cause and specified comorbid conditions. Exposure of SCS will be measured from index date to incidence of the outcome or to the end of a patient’s observation. SCS use will be defined as exposure vs. non-exposure, cumulative dose, average total daily dose, duration of long-term use, acute courses and intermittent use

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**Study status**

Planned

## Research institutions and networks

## Institutions

### Observational & Pragmatic Research Institute Pte (OPRI)

United Kingdom

**First published:** 06/10/2015

**Last updated:** 19/08/2024

Institution | Educational Institution | Laboratory/Research/Testing facility

ENCePP partner

## Contact details

**Study institution contact**

David Price

Study contact

dprice@opri.sg

**Primary lead investigator**

David Price

Primary lead investigator

## Study timelines

**Date when funding contract was signed**

Planned: 06/11/2019

**Study start date**
Planned: 28/08/2020

**Data analysis start date**
Planned: 28/08/2020

**Date of final study report**
Planned: 01/09/2022

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

AstraZeneca

## 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 type:**

Non-interventional study

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**Scope of the study:**

Assessment of risk minimisation measure implementation or effectiveness

Drug utilisation

**Main study objective:**

To evaluate patterns of use, risk of comorbidities associated with COPD-related systemic corticosteroids use, and related cost impact on COPD patients in the CPRD database

## Study Design

**Non-interventional study design**

Cohort

## Study drug and medical condition

**Anatomical Therapeutic Chemical (ATC) code**

(H02) CORTICOSTEROIDS FOR SYSTEMIC USE

CORTICOSTEROIDS FOR SYSTEMIC USE

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**Medical condition to be studied**

Chronic obstructive pulmonary disease

## Population studied

**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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**Estimated number of subjects**

193320

## Study design details

**Outcomes**

We aim to: 1.Describe patterns of COPD-related SCS use 2.Measure the association between COPD-related SCS exposure and (1) the incidence of outcome morbidities (2) the worsening or recurrence of outcome morbidities 3.Quantify annualised and longitudinal healthcare resource utilisation and associated costs to the healthcare system due to SCS-related all-cause and specified comorbid conditions, To describe: 1.patterns of all-cause SCS 2.longitudinal SCS exposure pre- and post diagnosis of COPD 3.cumulative OCS dose per moderate COPD exacerbation 4.patients who are not on maintenance therapy pre- and post COPD diagnosis 5.changes in maintenance therapy by SCS 6.correlation of SCS with changes in blood eosinophil counts 7.potential SCS dose thresholds at which comorbidities occurs

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**Data analysis plan**

For each SCS-related condition, a multivariable Cox proportional hazard model will be considered with time-depending or -varying exposure measures and confounders accounted for at baseline. Each analysis will be adjusted for the

variables identified as residual confounders during the baseline analysis. Time to event will be defined as the time from index date up to the onset of SCS-related conditions. The HCRU outcomes and associated costs to the healthcare system will be described for each of the resource components and SCS-related all-cause and specified comorbid conditions for all complete years of follow-up from the index date until the end of the last completed follow-up year, separately for each risk cohort. Generalised estimating equations with cluster robust standard errors, log link and gamma distribution will be used to estimate the effect of different strata of SCS exposure on annualised HCRU or costs.

# Data management

## Data sources

**Data source(s)**

Clinical Practice Research Datalink

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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

**Check completeness**

Unknown

**Check stability**

Unknown

**Check logical consistency**

Unknown

## Data characterisation

**Data characterisation conducted**

No