

# Evaluation of COPD Control and its Clinical Implications in a Real-Life UK Primary Care Population

**First published:** 16/08/2015

**Last updated:** 02/07/2024

Study

Finalised

## Administrative details

### EU PAS number

EUPAS10679

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### Study ID

26337

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### DARWIN EU® study

No

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### Study countries

☐ United Kingdom

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## Study description

This objective of this study, proposed by Dr. Marc Miravittles at the Vall d' Hebron University Hospital (Barcelona, Spain), is to validate the concept of Control in COPD, as outlined in Soler- Cataluna et al. 2014. The protocol has been developed, and the study will be overseen by an international steering committee comprising members of REG's COPD Control Working Group. The protocol will make use of the OPCRd and the study will serve as an important hypothesis-generating pilot for an international prospective trial commencing later in the year.

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## Study status

Finalised

## Research institutions and networks

### Institutions

University Hospital Vall d'Hebron (HUVH)

☐ Spain

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

**Last updated:** 01/02/2024

Institution

Educational Institution

Hospital/Clinic/Other health care facility

### Networks

Respiratory Effectiveness Group (REG)

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

**First published:** 07/07/2021

**Last updated:** 04/06/2024

Network

ENCePP partner

## Contact details

### Study institution contact

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Study contact

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### Primary lead investigator

Marc Miravitless

Primary lead investigator

## Study timelines

**Date when funding contract was signed**

Planned: 01/09/2015

Actual: 02/07/2015

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**Study start date**

Planned: 01/09/2015

Actual: 01/08/2015

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**Date of final study report**

Planned: 13/11/2015

Actual: 26/01/2016

## Sources of funding

- Other

## More details on funding

Respiratory Effectiveness Group (REG)

## Study protocol

[REG\\_COPD Control\\_UK Pilot Validation\\_300615\\_Protocol \(1\).pdf](#)(1.29 MB)

## Regulatory

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

Unknown

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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)

Other

#### **If 'other', further details on the scope of the study**

Testing the validity/effectiveness of the concept of COPD Control for potential patient management

#### **Data collection methods:**

Secondary use of data

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#### **Main study objective:**

The purpose of this study is to validate the concept of Control in COPD, as outlined in Soler- Cataluna et al. 2014. First, COPD patients treated in UK

routine primary care will be characterised in terms of their control. Second, we will evaluate the clinical implications of control status in terms of COPD treatment management.

## Study Design

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

Cohort

Other

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### **Non-interventional study design, other**

Observational, historical database study

## Study drug and medical condition

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

Chronic obstructive pulmonary disease

## Population studied

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

- Patients who have a COPD diagnosis:
  - o Physician-diagnosed COPD (presence of a COPD Read code); and/or
  - o Spirometry-defined COPD: post-bronchodilator FEV1/FVC<0.7
- Aged  $\geq 40$  years
- Current or ex-smokers
- Recorded COPD Questionnaire data

- $\geq 3$  months' continuous clinical records immediately prior to the index date
  - $\geq 1$  year of continuous clinical records immediately following the index date
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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**

300

## **Study design details**

### **Outcomes**

The primary endpoint of the study is the difference between patients controlled vs uncontrolled at baseline / index date in terms of: (a) Time to first COPD exacerbation (b) Exacerbation rate over the 1-year outcome period, Secondary endpoints

1. Annual rate of COPD exacerbations in patients controlled vs non-controlled at index date.
2. Time to the first exacerbation in patients controlled and non controlled at baseline
3. Demographic and clinical characteristics associated with poor COPD control, specifically: (a) Age (b) Sex (c) Height (d) Weight (e) Therapy (f) Airway obstruction (g) Smoking history

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## Data analysis plan

Statistically significant results will be defined as  $p < 0.05$  and trends as  $0.05 \leq p < 0.10$ . Association between COPD control status and the outcome period will be modeled using appropriate statistical methods. The statistical approach to be outlined in the statistical analysis plan (SAP) and will be approved by the lead investigator before the study commences. To evaluate the interaction of different patient (clinical and demographic) characteristics on the association between control status and outcomes, results will be stratified by:

- Age
- Sex
- Height
- Weight
- Therapy (at index date)
- Airway obstruction
- Smoking history (pack years)

## Documents

### Study publications

[Miravitlles M, Sliwinski P, Rhee CK, Costello RW, Carter V, Tan J, Lapperre TS,...](#)

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## Data management

## Data sources

### Data source(s), other

Optimum Patient Care Research Database United Kingdom

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### Data sources (types)

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

[Other](#)

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

The OPCRCD comprises data extracted through the Optimum Patient Care (OPC) Clinical Service Evaluation and includes anonymised electronic medical records (EMRs) and patients' responses to disease-specific questionnaires. Data from these EMRs will be used.

# 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**

Unknown