# 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

**Study ID**

26337

**DARWIN EU® study**

No

**Study countries**

United Kingdom

**Study description**

This objective of this study, proposed by Dr. Marc Miravitlles 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.

**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**

David Price david@rirl.org

Study contact

david@rirl.org

**Primary lead investigator**

Marc Miravitless

Primary lead investigator

## Study timelines

**Date when funding contract was signed**
Planned: 01/09/2015

Actual: 02/07/2015

---

**Study start date**
Planned: 01/09/2015

Actual: 01/08/2015

---

**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

---

**Is the study required by a Risk Management Plan (RMP)?**

Not applicable

# Methodological aspects

## Study type

## Study type list

**Study topic:**

Disease /health condition

---

**Study type:**

Non-interventional study

---

**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

---

**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 or 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

---

**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 ≥40 years

• Current or ex-smokers

• Recorded COPD Questionnaire data

• ≥3 months’ continuous clinical records immediately prior to the index date

• ≥1 year of continuous clinical records immediately following the index date

**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**

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 exacerbationb) Exacerbation rate over the 1-year outcome period, Secondary endpoints1. 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 baseline3. 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

**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,...

# 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), other**

Optimum Patient Care Research Database United Kingdom

**Data sources (types)**

Electronic healthcare records (EHR)

Other

**Data sources (types), other**

The OPCRD 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

**Check completeness**

Unknown

**Check stability**

Unknown

**Check logical consistency**

Unknown

## Data characterisation

**Data characterisation conducted**

Unknown